

US3642072 (Prod: University of California San Diego)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:12:20

All time stamps listed in this document are displayed in GMT

US3642072

Form: Participant Creation

Data signed: (b) (4) 13 Feb 2021 02:37:11

Generated On: 10 Jun 2021 09:12:20

Participant ID

US3642072

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

US3642072

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:37:12

Generated On: 10 Jun 2021 09:12:20

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

US3642072

Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 02:37:12

Generated On: 10 Jun 2021 09:12:20

Date of Birth (MMM yyyy)	(b) (6) 1940
Age	79
Age Units	YEARS
Age (Derived)	79
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) 13 Feb 2021 02:37:12

Generated On: 10 Jun 2021 09:12:20

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

US3642072

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 02:37:12

Generated On: 10 Jun 2021 09:12:20

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Feb 2021 02:37:12

Generated On: 10 Jun 2021 09:12:20

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 06 Mar 2021 01:40:20

Generated On: 10 Jun 2021 09:12:20

Condition	MIGRAINES
Start date (dd MMM yyyy)	UN UNK 1980
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 1980
Start Year (derived)	1980
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3642072

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 06 Mar 2021 01:40:20

Generated On: 10 Jun 2021 09:12:20

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

US3642072

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 06 Mar 2021 01:40:20

Generated On: 10 Jun 2021 09:12:20

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

US3642072

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 06 Mar 2021 01:40:20

Generated On: 10 Jun 2021 09:12:20

Condition	HYPER CHOLESTEROL
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

US3642072

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 06 Mar 2021 01:40:20

Generated On: 10 Jun 2021 09:12:20

Condition	BONE PAIN (BACK)
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)	_____

US3642072

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 06 Mar 2021 01:40:20

Generated On: 10 Jun 2021 09:12:20

Condition	POST-MENOPAUSAL
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3642072

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 02:37:12

Generated On: 10 Jun 2021 09:12:20

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	01 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	14:51 (24 HR)
Vital Signs Date and Time (derived)	01 SEP 2020 14:51
Height (<i>xxx.x</i>)	163 cm
Weight (<i>xxx.x</i>)	56.1 kg
BMI (<i>xxx.x</i>)	21.11483 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:37:12

Generated On: 10 Jun 2021 09:12:20

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

01 SEP 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) 13 Feb 2021 02:37:11

Generated On: 10 Jun 2021 09:12:20

Date of assessment (dd MMM yyyy) 01 SEP 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 02:37:12

Generated On: 10 Jun 2021 09:12:20

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) 13 Feb 2021 02:37:12

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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) 13 Feb 2021 02:37:12

Generated On: 10 Jun 2021 09:12:20

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	1 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	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 02:37:12

Generated On: 10 Jun 2021 09:12:20

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

What was the participant's randomization number? 189487

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) 13 Feb 2021 02:37:12

Generated On: 10 Jun 2021 09:12:20

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) 13 Feb 2021 02:37:12

Generated On: 10 Jun 2021 09:12:20

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	01 SEP 2020
Time of assessment (00:00-23:59)	14:51 (24 HR)
Vital Signs Date and Time (derived)	01 SEP 2020 14:51
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 02:37:12

Generated On: 10 Jun 2021 09:12:20

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	01 SEP 2020
Time of assessment (00:00-23:59)	16:43 (24 HR)
Vital Signs Date and Time (derived)	01 SEP 2020 16:43
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:37:12

Generated On: 10 Jun 2021 09:12:20

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) 13 Feb 2021 02:37:12

Generated On: 10 Jun 2021 09:12:20

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) 1 SEP 2020

What was the treatment time? (00:00-23:59) 16:14 (24 HR)

Treatment Date and Time (derived) 1 SEP 2020 16:14

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) 13 Feb 2021 02:37:12

Generated On: 10 Jun 2021 09:12:20

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

01 SEP 2020

Collection time (00:00-23:59)

15:21 (24 HR)

Collection date and time (derived)

01 SEP 2020 15:21

US3642072

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 02:37:12

Generated On: 10 Jun 2021 09:12:20

Collection date (dd MMM yyyy)			01 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:25	01 SEP 2020 15:25
Nasopharyngeal Swab 2	No		

US3642072

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:37:12

Generated On: 10 Jun 2021 09:12:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642072

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 SEP 2020 16:36

PC Open Date & Time

01 SEP 2020 16:34

PC Close Date & Time

01 SEP 2020 19:04

US3642072

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.0 °F

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

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

PC Time Stamp	01 SEP 2020 20:46
PC Open Date & Time	01 SEP 2020 19:59
PC Close Date & Time	02 SEP 2020 11:59

US3642072

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:12:20

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

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

02 SEP 2020 12:14

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3642072

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:12:20

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

96.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 14:14

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3642072

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.6 °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

04 SEP 2020 12:35

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3642072

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:12:20

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

05 SEP 2020 12:06

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3642072

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 12:04

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3642072

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:12:20

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

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 SEP 2020 13:09

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3642072

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:12:20

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

01 SEP 2020 16:37

PC Open Date & Time

01 SEP 2020 16:34

PC Close Date & Time

01 SEP 2020 19:04

US3642072

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 SEP 2020 20:47

PC Open Date & Time

01 SEP 2020 19:59

PC Close Date & Time

02 SEP 2020 11:59

US3642072

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 SEP 2020 12:14

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3642072

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 14:14

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3642072

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:12:20

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

04 SEP 2020 12:35

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3642072

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:12:20

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

05 SEP 2020 12:07

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3642072

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:12:20

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

06 SEP 2020 12:05

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3642072

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:12:20

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

07 SEP 2020 13:10

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:12:20

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 ☐

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:12:20

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

No ☒

Yes ☐

PC Time stamp	01 SEP 2020 16:37
PC Open Date & Time	01 SEP 2020 16:34
PC Close Date & Time	01 SEP 2020 19:04

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:12:20

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 ☐

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:12:20

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

No ☒

Yes ☐

PC Time stamp	01 SEP 2020 20:47
PC Open Date & Time	01 SEP 2020 19:59
PC Close Date & Time	02 SEP 2020 11:59

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:12:20

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 ☒

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:12:20

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 12:15
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:12:20

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 ☒

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:12:20

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 14:14
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:12:20

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 ☒

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:12:20

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 12:36
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:12:20

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)

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:12:20

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 12:07
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:12:20

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 ☒

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:12:20

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 12:05
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:12:20

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 ☒

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:12:20

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 13:10
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3642072

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:37:11

Generated On: 10 Jun 2021 09:12:20

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3642072

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:37:11

Generated On: 10 Jun 2021 09:12:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642072

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:37:11

Generated On: 10 Jun 2021 09:12:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3642072

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:37:11

Generated On: 10 Jun 2021 09:12:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642072

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:37:11

Generated On: 10 Jun 2021 09:12:20

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

US3642072

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:37:11

Generated On: 10 Jun 2021 09:12:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642072

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:37:12

Generated On: 10 Jun 2021 09:12:20

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 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

US3642072

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 02:37:12

Generated On: 10 Jun 2021 09:12:20

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)	29 SEP 2020
Time of assessment (00:00-23:59)	14:26 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 14:26
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)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG

US3642072

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 02:37:12

Generated On: 10 Jun 2021 09:12:20

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	29 SEP 2020
Time of assessment (00:00-23:59)	16:32 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 16:32
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 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

US3642072

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:37:12

Generated On: 10 Jun 2021 09:12:20

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 SEP 2020

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

US3642072

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 02:37:12

Generated On: 10 Jun 2021 09:12:20

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) 29 SEP 2020

What was the treatment time? (00:00-23:59) 15:59 (24 HR)

Treatment Date and Time (derived) 29 SEP 2020 15:59

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

US3642072

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 02:37:12

Generated On: 10 Jun 2021 09:12:20

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	29 SEP 2020
Collection time (00:00-23:59)	15:00 (24 HR)
Collection date and time (derived)	29 SEP 2020 15:00

US3642072

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 02:37:12

Generated On: 10 Jun 2021 09:12:20

Collection date (dd MMM yyyy)			29 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:03	29 SEP 2020 15:03
Nasopharyngeal Swab 2	No		

US3642072

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:37:12

Generated On: 10 Jun 2021 09:12:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642072

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐
No ☒

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

PC Time Stamp 29 SEP 2020 16:20

PC Open Date & Time 29 SEP 2020 16:19

PC Close Date & Time 29 SEP 2020 18:49

US3642072

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:12:20

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 96.9 °F

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

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

PC Time Stamp	29 SEP 2020 19:57
PC Open Date & Time	29 SEP 2020 19:44
PC Close Date & Time	30 SEP 2020 11:59

US3642072

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:12:20

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

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 SEP 2020 15:29

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3642072

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:12:20

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

96.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 OCT 2020 13:31

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3642072

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:12:20

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

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 OCT 2020 14:27

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3642072

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 OCT 2020 16:30

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3642072

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:12:20

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

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 OCT 2020 15:00

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3642072

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:12:20

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

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 OCT 2020 14:55

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3642072

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:12:20

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

29 SEP 2020 16:21

PC Open Date & Time

29 SEP 2020 16:19

PC Close Date & Time

29 SEP 2020 18:49

US3642072

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 SEP 2020 19:57

PC Open Date & Time

29 SEP 2020 19:44

PC Close Date & Time

30 SEP 2020 11:59

US3642072

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:12:20

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

30 SEP 2020 15:30

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3642072

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 OCT 2020 13:31

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3642072

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 OCT 2020 14:28

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3642072

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 OCT 2020 16:30

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3642072

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 OCT 2020 15:00

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3642072

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 OCT 2020 14:55

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:12:20

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 ☐

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:12:20

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

No ☒

Yes ☐

PC Time stamp	29 SEP 2020 16:21
PC Open Date & Time	29 SEP 2020 16:19
PC Close Date & Time	29 SEP 2020 18:49

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:12:20

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 ☐

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:12:20

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

No ☒

Yes ☐

PC Time stamp	29 SEP 2020 19:58
PC Open Date & Time	29 SEP 2020 19:44
PC Close Date & Time	30 SEP 2020 11:59

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:12:20

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)

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:12:20

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 15:31
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:12:20

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 ☒

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:12:20

Yes <input type="checkbox"/>	
PC Time stamp	01 OCT 2020 13:32
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:12:20

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 ☒

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:12:20

Yes <input type="checkbox"/>	
PC Time stamp	02 OCT 2020 14:28
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:12:20

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 16:31
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:12:20

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 ☒

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:12:20

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 15:00
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:12:20

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 ☒

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:12:20

Yes <input type="checkbox"/>	
PC Time stamp	05 OCT 2020 14:56
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3642072

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:37:11

Generated On: 10 Jun 2021 09:12:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3642072

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:37:11

Generated On: 10 Jun 2021 09:12:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642072

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:37:11

Generated On: 10 Jun 2021 09:12:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3642072

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:37:11

Generated On: 10 Jun 2021 09:12:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642072

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:37:11

Generated On: 10 Jun 2021 09:12:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3642072

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:37:11

Generated On: 10 Jun 2021 09:12:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642072

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:37:12

Generated On: 10 Jun 2021 09:12:20

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	27 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

US3642072

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 02:37:12

Generated On: 10 Jun 2021 09:12:20

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	27 OCT 2020
Time of assessment (00:00-23:59)	15:20 (24 HR)
Vital Signs Date and Time (derived)	27 OCT 2020 15:20
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3642072

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:37:12

Generated On: 10 Jun 2021 09:12:20

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

27 OCT 2020

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

US3642072

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 02:37:12

Generated On: 10 Jun 2021 09:12:20

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	27 OCT 2020
Collection time (00:00-23:59)	15:46 (24 HR)
Collection date and time (derived)	27 OCT 2020 15:46

US3642072

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:37:12

Generated On: 10 Jun 2021 09:12:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642072

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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	01 NOV 2020 05:46:16
Patient Cloud Open Date & Time	01 NOV 2020 00:01
Patient Cloud Close Date & Time	05 NOV 2020 23:59

US3642072

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

09 NOV 2020 17:35:36

Patient Cloud Open Date & Time

08 NOV 2020 00:01

Patient Cloud Close Date & Time

12 NOV 2020 23:59

US3642072

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

17 NOV 2020 12:00:51

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 NOV 2020 00:01
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Patient Cloud Close Date & Time	23 NOV 2020 23:59
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US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	30 NOV 2020 20:51:17
Patient Cloud Open Date & Time	26 NOV 2020 00:01
Patient Cloud Close Date & Time	30 NOV 2020 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 DEC 2020 00:10:37
Patient Cloud Open Date & Time	03 DEC 2020 00:01
Patient Cloud Close Date & Time	07 DEC 2020 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	10 DEC 2020 16:17:13
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 DEC 2020 12:00:38

Patient Cloud Open Date & Time

17 DEC 2020 00:01

Patient Cloud Close Date & Time

21 DEC 2020 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 DEC 2020 11:26:08

Patient Cloud Open Date & Time

24 DEC 2020 00:01

Patient Cloud Close Date & Time

28 DEC 2020 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 DEC 2020 09:04:44

Patient Cloud Open Date & Time

31 DEC 2020 00:01

Patient Cloud Close Date & Time

04 JAN 2021 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 JAN 2021 14:21:18
Patient Cloud Open Date & Time	07 JAN 2021 00:01
Patient Cloud Close Date & Time	11 JAN 2021 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

15 JAN 2021 06:16:53

Patient Cloud Open Date & Time

14 JAN 2021 00:01

Patient Cloud Close Date & Time

18 JAN 2021 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 JAN 2021 12:01:02
Patient Cloud Open Date & Time	21 JAN 2021 00:01
Patient Cloud Close Date & Time	25 JAN 2021 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 JAN 2021 18:23:43

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 FEB 2021 16:14:03
Patient Cloud Open Date & Time	04 FEB 2021 00:01
Patient Cloud Close Date & Time	08 FEB 2021 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 FEB 2021 10:01:04
Patient Cloud Open Date & Time	11 FEB 2021 00:01
Patient Cloud Close Date & Time	15 FEB 2021 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

18 FEB 2021 08:01:16

Patient Cloud Open Date & Time

18 FEB 2021 00:01

Patient Cloud Close Date & Time

22 FEB 2021 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

27 FEB 2021 20:06:21

Patient Cloud Open Date & Time

25 FEB 2021 00:01

Patient Cloud Close Date & Time

01 MAR 2021 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

04 MAR 2021 10:56:48

Patient Cloud Open Date & Time

04 MAR 2021 00:01

Patient Cloud Close Date & Time

08 MAR 2021 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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	11 MAR 2021 17:34:22
Patient Cloud Open Date & Time	11 MAR 2021 00:01
Patient Cloud Close Date & Time	15 MAR 2021 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

20 MAR 2021 13:04:27

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

25 MAR 2021 10:36:15

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

02 APR 2021 08:39:43

Patient Cloud Open Date & Time

01 APR 2021 00:01

Patient Cloud Close Date & Time

05 APR 2021 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

10 APR 2021 16:46:59

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 APR 2021 07:02:40

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 APR 2021 11:48:19

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

29 APR 2021 07:56:07

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

[Patient Cloud Open Date & Time](#)

06 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

DAY 257

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

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

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

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

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

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

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

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

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

[Patient Cloud Open Date & Time](#)

13 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

[Patient Cloud Open Date & Time](#)

27 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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"/>

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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"/>

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

[Patient Cloud Open Date & Time](#)

10 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

[Patient Cloud Open Date & Time](#)

17 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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"/>

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

[Patient Cloud Open Date & Time](#)

24 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

[Patient Cloud Open Date & Time](#)

01 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

[Patient Cloud Open Date & Time](#)

08 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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"/>

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 JUL 2021 00:01
Patient Cloud Close Date & Time	19 JUL 2021 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

[Patient Cloud Open Date & Time](#)

22 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 JUL 2021 00:01
Patient Cloud Close Date & Time	02 AUG 2021 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 AUG 2021 00:01
Patient Cloud Close Date & Time	16 AUG 2021 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

[Patient Cloud Open Date & Time](#)

19 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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"/>

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 AUG 2021 00:01
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Patient Cloud Close Date & Time	30 AUG 2021 23:59
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US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

DAY 369

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

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

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

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

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

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

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

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

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

DAY 376

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

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

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

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

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

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

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 ☐

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

[Patient Cloud Open Date & Time](#)

09 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

DAY 383

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

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

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

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

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

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

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

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

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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"/>

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

[Patient Cloud Open Date & Time](#)

07 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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"/>

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 OCT 2021 00:01
Patient Cloud Close Date & Time	18 OCT 2021 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

Patient Cloud Open Date & Time	21 OCT 2021 00:01
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Patient Cloud Close Date & Time	25 OCT 2021 23:59
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US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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 ☐

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 NOV 2021 00:01
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Patient Cloud Close Date & Time	15 NOV 2021 23:59
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US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

DAY 453

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

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

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

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

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

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

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

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

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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"/>

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

[Patient Cloud Close Date & Time](#)

06 DEC 2021 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 DEC 2021 00:01
Patient Cloud Close Date & Time	13 DEC 2021 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 DEC 2021 00:01
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Patient Cloud Close Date & Time	20 DEC 2021 23:59
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US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

27 DEC 2021 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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"/>

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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 ☐

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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 ☐

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

[Patient Cloud Close Date & Time](#)

31 JAN 2022 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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 ☐

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 FEB 2022 00:01

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14 FEB 2022 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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 ☐

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 FEB 2022 00:01

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21 FEB 2022 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 FEB 2022 00:01

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28 FEB 2022 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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 ☐

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

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07 MAR 2022 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

DAY 558

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

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

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

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

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

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

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

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

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

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14 MAR 2022 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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 ☐

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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 ☐

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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 ☐

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

[Patient Cloud Close Date & Time](#)

18 APR 2022 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 APR 2022 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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"/>

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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"/>

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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"/>

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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 ☐

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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"/>

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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 ☐

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

[Patient Cloud Close Date & Time](#)

18 JUL 2022 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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"/>

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2022 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 AUG 2022 00:01
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Patient Cloud Close Date & Time	15 AUG 2022 23:59
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US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 AUG 2022 00:01
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Patient Cloud Close Date & Time	22 AUG 2022 23:59
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US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 AUG 2022 00:01
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Patient Cloud Close Date & Time	29 AUG 2022 23:59
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US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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"/>

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 SEP 2022 00:01
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Patient Cloud Close Date & Time	19 SEP 2022 23:59
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US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

DAY 761

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

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

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

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

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

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

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

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

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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"/>

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

[Patient Cloud Close Date & Time](#)

10 OCT 2022 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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 ☐

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

[Patient Cloud Close Date & Time](#)

17 OCT 2022 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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 ☐

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	20 OCT 2022 00:01
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Patient Cloud Close Date & Time	24 OCT 2022 23:59
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US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

27 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

31 OCT 2022 23:59

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

[Patient Cloud Close Date & Time](#)

07 NOV 2022 23:59

US3642072

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:12:20

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 20:06:35

US3642072

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:37:11

Generated On: 10 Jun 2021 09:12:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3642072

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:37:11

Generated On: 10 Jun 2021 09:12:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642072

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:37:11

Generated On: 10 Jun 2021 09:12:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3642072

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:37:11

Generated On: 10 Jun 2021 09:12:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642072

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:37:11

Generated On: 10 Jun 2021 09:12:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3642072

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:37:11

Generated On: 10 Jun 2021 09:12:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642072

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 06 Mar 2021 01:40:20

Generated On: 10 Jun 2021 09:12:20

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 01 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3642072

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 06 Mar 2021 01:40:20

Generated On: 10 Jun 2021 09:12:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642072

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 21:16:54

Generated On: 10 Jun 2021 09:12:20

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

Visit date (dd MMM yyyy)	18 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3642072

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 03 Apr 2021 23:27:44

Generated On: 10 Jun 2021 09:12:20

Were vital signs assessed? Yes ☐
No ☒

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 ☐
Axillary ☐
Other ☐

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 _____

Height (derived) _____

Weight (derived) _____

US3642072

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 21:16:54

Generated On: 10 Jun 2021 09:12:20

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.

US3642072

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Mar 2021 21:16:54

Generated On: 10 Jun 2021 09:12:20

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	18 MAR 2021
Collection time (00:00-23:59)	14:15 (24 HR)
Collection date and time (derived)	18 MAR 2021 14:15

US3642072

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 21:16:54

Generated On: 10 Jun 2021 09:12:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642072

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:21:10

Generated On: 10 Jun 2021 09:12:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3642072

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:21:10

Generated On: 10 Jun 2021 09:12:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642072

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:12:20

Was Contact Attempted? Yes ☐
No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3642072

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:12:20

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3642072

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:12:20

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"/>

US3642072

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:12:20

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3642072

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

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:37:11

Generated On: 10 Jun 2021 09:12:20

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

Visit date (dd MMM yyyy)	16 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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US3642072

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

Form: Unblinding

Data signed: (b) (4) 19 Apr 2021 18:01:49

Generated On: 10 Jun 2021 09:12:20

Date of updated informed consent (<i>dd MMM yyyy</i>)	16 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input checked="" type="radio"/> Amendment 6 or later <input type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	28 DEC 2020
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3642072

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 26 Mar 2021 21:16:54

Generated On: 10 Jun 2021 09:12:20

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3642072

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Mar 2021 21:16:54

Generated On: 10 Jun 2021 09:12:20

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	16 JAN 2021
Time of assessment (00:00-23:59)	13:22 (24 HR)
Vital Signs Date and Time (derived)	16 JAN 2021 13:22
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)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3642072

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Mar 2021 21:16:54

Generated On: 10 Jun 2021 09:12:20

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
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)	16 JAN 2021
Time of assessment (00:00-23:59)	16:05 (24 HR)
Vital Signs Date and Time (derived)	16 JAN 2021 16:05
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)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3642072

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

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:37:11

Generated On: 10 Jun 2021 09:12:20

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.

US3642072

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

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 02:37:11

Generated On: 10 Jun 2021 09:12:20

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 16 JAN 2021

What was the treatment time? (00:00-23:59) 15:34 (24 HR)

Treatment Date and Time (derived) 16 JAN 2021 15:34

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

US3642072

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Apr 2021 20:50:19

Generated On: 10 Jun 2021 09:12:20

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

16 JAN 2021

Collection time (00:00-23:59)

15:05 (24 HR)

Collection date and time (derived)

16 JAN 2021 15:05

US3642072

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 13 Feb 2021 02:37:11

Generated On: 10 Jun 2021 09:12:20

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	16 JAN 2021
Collection time (00:00 - 23:59)	15:00
Collection Date and Time (derived)	16 JAN 2021 15:00

US3642072

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

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:37:11

Generated On: 10 Jun 2021 09:12:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642072

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:37:11

Generated On: 10 Jun 2021 09:12:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3642072

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:37:11

Generated On: 10 Jun 2021 09:12:20

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

US3642072

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 21:04:27

Generated On: 10 Jun 2021 09:12:20

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3642072

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 06 Mar 2021 01:40:20

Generated On: 10 Jun 2021 09:12:20

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)	11 FEB 2021
Time of assessment (00:00-23:59)	14:31 (24 HR)
Vital Signs Date and Time (derived)	11 FEB 2021 14:31
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)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	56 mmHg
Diastolic Blood Pressure units	MMHG

US3642072

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 06 Mar 2021 01:40:20

Generated On: 10 Jun 2021 09:12:20

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)	11 FEB 2021
Time of assessment (00:00-23:59)	16:11 (24 HR)
Vital Signs Date and Time (derived)	11 FEB 2021 16:11
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)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	58 mmHg
Diastolic Blood Pressure units	MMHG

US3642072

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 21:04:27

Generated On: 10 Jun 2021 09:12:20

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.

US3642072

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 21:04:27

Generated On: 10 Jun 2021 09:12:20

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 11 FEB 2021

What was the treatment time? (00:00-23:59) 15:40 (24 HR)

Treatment Date and Time (derived) 11 FEB 2021 15:40

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

US3642072

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 21:04:27

Generated On: 10 Jun 2021 09:12:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642072

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 21:04:27

Generated On: 10 Jun 2021 09:12:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3642072

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 21:04:27

Generated On: 10 Jun 2021 09:12:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3642072

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 21:16:54

Generated On: 10 Jun 2021 09:12:20

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3642072

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Mar 2021 21:16:54

Generated On: 10 Jun 2021 09:12:20

Were vital signs assessed? Yes ☐
No ☒

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 ☐
Axillary ☐
Other ☐

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 _____

Height (derived) _____

Weight (derived) _____

US3642072

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 21:16:54

Generated On: 10 Jun 2021 09:12:20

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.

US3642072

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Mar 2021 21:16:54

Generated On: 10 Jun 2021 09:12:20

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	18 MAR 2021
Collection time (<i>00:00-23:59</i>)	14:15 (24 HR)
Collection date and time (derived)	18 MAR 2021 14:15

US3642072

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 13 Feb 2021 02:37:11

Generated On: 10 Jun 2021 09:12:20

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3642072

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 21:21:10

Generated On: 10 Jun 2021 09:12:20

AEID	USA-US109-2020-MRNA-1273-P30 1000004
Adverse event	HIP FRACTURE S/P FALL
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	27 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	30 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	27 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	30 NOV 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 21:21:10

Generated On: 10 Jun 2021 09:12:20

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

US3642072

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 21:21:10

Generated On: 10 Jun 2021 09:12:20

SUBJECT REPORTS THAT ON FRIDAY MORNING 27NOV2020 SHE FELL AND SHE DID NOT HIT HER HEAD OR LOOSE CONSCIOUSNESS (FALL ACCIDENTAL). SHE FELL WHILE WALKING AT THE BEACH AND FRACTURED HER LEFT HIP AND WAS TAKEN TO SCRIPPS GREEN HOSPITAL WHERE SHE WAS ADMITTED TO THE HOSPITAL AND UNDERWENT A HIP REPLACEMENT ON 28NOV2020. SHE WAS TESTED FOR COVID PRIOR TO SURGERY AND TESTED NEGATIVE. SHE HAS NO SIGNS OR SYMPTOMS OF COVID AT THIS TIME. SHE SAID SHE DOES NOT KNOW ANY FURTHER DETAILS BUT SHE SIGNED A MEDICAL RELEASE FORM WHEN ENROLLING SO WE ARE WELCOME TO REQUEST THE RECORDS FROM SCRIPPS. SHE IS NOW TAKING DAILY ASPIRIN 325MG DAILY. SHE WAS ALSO PRESCRIBED OXYCODONE 5MG Q4-6HOURS PRN BUT SHE REPORTS SHE IS TAKING IT ABOUT EVERY 7 HOURS. UPDATE: PATIENT FOLLOWED UP WITH ORTHOPEDIC SURGEON ON 02MAR2021. ALL PAIN ASSOCIATED WITH AE RESOLVED, PAIN MEDICATIONS DISCONTINUED. MD IS HAPPY WITH THE PATIENTS PROGRESS AND THEY WILL FOLLOW UP AGAIN IN APPROX 3 MONTHS.

Serious Adverse Event Derived (CSA Programming Field Only)

1

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 21:21:10

Generated On: 10 Jun 2021 09:12:20

Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3642072

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 21:21:10

Generated On: 10 Jun 2021 09:12:20

AEID	USA-US109-2020-MRNA-1273-P30 1000004
Adverse event	FALL (ACCIDENTAL)
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	27 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	27 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	27 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	30 NOV 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 21:21:10

Generated On: 10 Jun 2021 09:12:20

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

US3642072

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 21:21:10

Generated On: 10 Jun 2021 09:12:20

SUBJECT HAD ACCIDENTAL
FALL AT THE BEACH ON
27NOV2020. NO LOC. SUBJECT
DID NOT HIT HEAD. HIP
FRACTURE SUSTAINED AND
REQUIRED SURGERY (SEE CON
PROCEDURE) - SEE HIP
FRACTURE AE FOR
ADDITIONAL INFORMATION.

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3642072

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 21:21:10

Generated On: 10 Jun 2021 09:12:20

AEID

Adverse event

PRE-BASAL CELL CARCINOMA
SKIN LESION

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)

4 MAR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

16 MAR 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 21:21:10

Generated On: 10 Jun 2021 09:12:20

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input 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	

US3642072

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 21:21:10

Generated On: 10 Jun 2021 09:12:20

PATIENT SEEN BY THEIR
DERMATOLOGIST ON
04MAR2021 DUE TO A SMALL
SKIN LESION ON THEIR CHEST.
THE SKIN LESION WAS THEN
DIAGNOSED AS PRE-BASAL
CELL CARCINOMA. THE
SUBJECT WAS PRESCRIBED A
MEDICATED CREAM TO APPLY.
FLUOROURACIL (EFUDEX) 5%
APPLIED TOPICALLY ONCE
DAILY FOR TWO WEEKS FOR
PRE-BASAL CELL CARCINOMA
SKIN LESION STARTING ON
04MAR2021 AND STOPPED ON
16MAR2021. SUBJECT WILL
FOLLOW UP WITH
DERMATOLOGY ON
24MAR2021.
UPDATE: PATIENT REPORTS
LESION WAS RESOLVED AFTER
COMPLETING FLUOROURACIL
TREATMENT. SHE FOLLOWED
UP WITH DERM ON 24MAR2021
WHO AGREED LESION IS
RESOLVED. SHE WILL
CONTINUE WITH ROUTINE
DERM FOLLOW-UP, NEXT
SCHEDULED SEPT2021.

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)	

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 13 Feb 2021 02:37:11

Generated On: 10 Jun 2021 09:12:20

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

Yes ☒

No ☐

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

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 03 Apr 2021 23:27:44

Generated On: 10 Jun 2021 09:12:20

Name of Medication LEVOTHYROXINE

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROIDISM

Dose per administration 75

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

If dose unit is Other, specify MCG

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 03 Apr 2021 23:27:44

Generated On: 10 Jun 2021 09:12:20

	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 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 03 Apr 2021 23:27:44

Generated On: 10 Jun 2021 09:12:20

Name of Medication LOSARTAN

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 03 Apr 2021 23:27:44

Generated On: 10 Jun 2021 09:12:20

	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 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 03 Apr 2021 23:27:44

Generated On: 10 Jun 2021 09:12:20

Name of Medication LIPITOR

Prophylaxis Yes ☐
No ☒

Indication HIGH CHOLESTEROL

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 03 Apr 2021 23:27:44

Generated On: 10 Jun 2021 09:12:20

	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 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 03 Apr 2021 23:27:44

Generated On: 10 Jun 2021 09:12:20

Name of Medication ROBAXIN

Prophylaxis Yes ☐
No ☒

Indication BONE PAIN

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 03 Apr 2021 23:27:44

Generated On: 10 Jun 2021 09:12:20

	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 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 03 Apr 2021 23:27:44

Generated On: 10 Jun 2021 09:12:20

Name of Medication IMITREX

Prophylaxis Yes ☐
No ☒

Indication MIGRAINES

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 03 Apr 2021 23:27:44

Generated On: 10 Jun 2021 09:12:20

	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 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 03 Apr 2021 23:27:44

Generated On: 10 Jun 2021 09:12:20

Name of Medication FLU VACCINE

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS FOR FLU

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 03 Apr 2021 23:27:44

Generated On: 10 Jun 2021 09:12:20

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		23 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		23 OCT 2020
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"/>

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 03 Apr 2021 23:27:44

Generated On: 10 Jun 2021 09:12:20

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication DVT PROPHYLAXIS

Dose per administration 325

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 03 Apr 2021 23:27:44

Generated On: 10 Jun 2021 09:12:20

	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)	28 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 03 Apr 2021 23:27:44

Generated On: 10 Jun 2021 09:12:20

Name of Medication OXYCODONE

Prophylaxis Yes ☐
No ☒

Indication HIP FRACTURE S/P FALL

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 03 Apr 2021 23:27:44

Generated On: 10 Jun 2021 09:12:20

	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)	28 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		02 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 03 Apr 2021 23:27:44

Generated On: 10 Jun 2021 09:12:20

Name of Medication OXYCONTIN

Prophylaxis Yes ☐
No ☒

Indication LEFT HIP REPLACEMENT SURGERY

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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US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 03 Apr 2021 23:27:44

Generated On: 10 Jun 2021 09:12:20

	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)	29 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		2 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 03 Apr 2021 23:27:44

Generated On: 10 Jun 2021 09:12:20

Name of Medication FLUOROURACIL 5% (EFUDEX)

Prophylaxis Yes ☐
No ☒

Indication PRE-BASAL CELL CARCINOMA
SKIN LESION

Dose per administration 1

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

If dose unit is Other, specify APPLICATION

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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US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 03 Apr 2021 23:27:44

Generated On: 10 Jun 2021 09:12:20

	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)	4 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	16 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3642072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 13 Feb 2021 02:37:11

Generated On: 10 Jun 2021 09:12:20

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3642072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 13 Feb 2021 02:37:11

Generated On: 10 Jun 2021 09:12:20

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
28 NOV 2020	LEFT HIP REPLACEMENT	Adverse Event	

US3642072

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:12:20

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

US3642072

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:12:20

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 ☐

US3642072

Folder: SAE USA-US109-2020-MRNA-1273-P301000004

Form: Safety Report Form

Data signed: (b) (4) 03 Apr 2021 23:27:44

Generated On: 10 Jun 2021 09:12:20

SAEID	USA-US109-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	STEPHEN
Investigator's Last Name	SPECTOR
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3642072

Folder: SAE USA-US109-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Data signed: (b) (4) 03 Apr 2021 23:27:44

Generated On: 10 Jun 2021 09:12:20

SAEID	USA-US109-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	STEPHEN
Investigator's Last Name	SPECTOR
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	03/DEC/2020 16:47
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3642072

Folder: SAE USA-US109-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Data signed: (b) (4) 03 Apr 2021 23:27:44

Generated On: 10 Jun 2021 09:12:20

SAEID	USA-US109-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	STEPHEN
Investigator's Last Name	SPECTOR
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	19/JAN/2021 09:31
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3642072

Folder: SAE USA-US109-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Data signed: (b) (4) 03 Apr 2021 23:27:44

Generated On: 10 Jun 2021 09:12:20

SAEID	USA-US109-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	STEPHEN
Investigator's Last Name	SPECTOR
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	31/MAR/2021 08:11
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3642072 (Prod: University of California San Diego)

US3642072

Form: Participant Creation

Generated On: 10 Jun 2021 09:12:20

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'US3642072'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 22:14:39

US3642072

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:12:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User closed query 'Per CDM: Please complete all applicable forms for this visit.' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Feb 2021 15:51:03
Query 'Per CDM: Please complete all applicable forms for this visit.' answered with 'forms completed' (Site from DM).	Benjamin Hull (b) (4) (b) (4)	01 Feb 2021 19:40:48
User opened query 'Per CDM: Please complete all applicable forms for this visit.' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 10:38:49
User entered 'Yes (Y)'	Megan Loughran (b) (4) (b) (4)	01 Sep 2020 23:17:01

US3642072

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '01 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 22:14:41

US3642072

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:12:20

[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 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Clinic (Clinic)'	Megan Loughran (b) (4)	01 Sep 2020 23:17:01

US3642072

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:12:20

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User entered 'SCRN'	System	01 Sep 2020 23:17:01

US3642072

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered (b) (6) 1940'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 22:14:41

US3642072

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:12:20

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '79'	(b) (4) Megan Loughran (b) (4)	10 Sep 2020 16:00:23

US3642072

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:12:20

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User entered 'YEARS'	System	10 Sep 2020 16:00:23

US3642072

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:12:20

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User entered '79'	System	01 Sep 2020 23:17:18

US3642072

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:12:20

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Female (F)'	(b) (4) Megan Loughran (b) (4)	10 Sep 2020 16:00:23

US3642072

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:12:20

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Megan Loughran (b) (4)	10 Sep 2020 16:00:23

US3642072

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:12:20

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'I'	(b) (4) Megan Loughran (b) (4)	10 Sep 2020 16:00:23

US3642072

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:12:20

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '0'	(b) (4) Megan Loughran (b) (4)	10 Sep 2020 16:00:23

US3642072

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:12:20

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '0'	(b) (4) Megan Loughran (b) (4)	10 Sep 2020 16:00:23

US3642072

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:12:20

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '0'	(b) (4) Megan Loughran (b) (4)	10 Sep 2020 16:00:23

US3642072

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:12:20

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '0'	(b) (4) Megan Loughran (b) (4)	10 Sep 2020 16:00:23

US3642072

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:12:20

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '0'	(b) (4) Megan Loughran (b) (4)	10 Sep 2020 16:00:23

US3642072

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:12:20

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered empty.	(b) (4) Megan Loughran (b) (4)	10 Sep 2020 16:00:23

US3642072

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:12:20

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '0'	(b) (4) Megan Loughran (b) (4)	10 Sep 2020 16:00:23

US3642072

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:12:20

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '0'	(b) (4) Megan Loughran (b) (4)	10 Sep 2020 16:00:23

US3642072

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '1 Sep 2020'	(b) (4) Megan Loughran (b) (4)	01 Sep 2020 23:17:18

US3642072

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User entered 'Sep 2020'	System	01 Sep 2020 23:17:18

US3642072

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User entered '2020'	System	01 Sep 2020 23:17:18

US3642072

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:12:20

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Amendment 3 (3)'	(b) (4) Megan Loughran (b) (4)	01 Sep 2020 23:17:18

US3642072

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Yes (Y)'	(b) (4) Megan Loughran (b) (4)	01 Sep 2020 23:17:18

US3642072

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered empty.	(b) (4) Megan Loughran (b) (4)	01 Sep 2020 23:17:18

US3642072

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:12:20

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered empty.	(b) (4) Megan Loughran (b) (4)	01 Sep 2020 23:17:18

US3642072

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:12:20

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'No (N)'	(b) (4) Megan Loughran (b) (4)	01 Sep 2020 23:17:18

US3642072

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:12:20

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 22:14:41

US3642072

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:12:20

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User entered 'I'	System	01 Sep 2020 23:17:28

US3642072

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Yes (Y)'	(b) (4) Megan Loughran (b) (4)	01 Sep 2020 23:17:28

US3642072

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:12:20

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Yes (Y)'	Son Do (b) (4)	22 Sep 2020 16:20:17

US3642072

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:12:20

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
User coded data point as SOC: Nervous system disorders, HLT: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine - version MedDRA\\23.0.	Coder Import (b) (4)	22 Sep 2020 16:22:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Sep 2020 16:22:42
Data point term sent to Coder	System	22 Sep 2020 16:21:32
User entered 'migraines'	Son Do (b) (4)	22 Sep 2020 16:20:38

US3642072

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
User entered 'UN UNK 1980'	Son Do (b) (4)	22 Sep 2020 16:20:38

US3642072

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:12:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
User entered '0'	Son Do (b) (4)	22 Sep 2020 16:20:38

US3642072

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:12:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
User entered 'Yes (Y)'	Son Do (b) (4)	22 Sep 2020 16:20:38

US3642072

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
User entered empty.	Son Do (b) (4)	22 Sep 2020 16:20:38

US3642072

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:12:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
User entered '0'	Son Do (b) (4)	22 Sep 2020 16:20:38

US3642072

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User entered 'Jan 1980'	System	22 Sep 2020 16:20:38

US3642072

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User entered '1980'	System	22 Sep 2020 16:20:38

US3642072

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User entered empty.	System	22 Sep 2020 16:20:38

US3642072

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User entered empty.	System	22 Sep 2020 16:20:38

US3642072

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:12:20

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
User coded data point as SOC: Endocrine disorders, HLT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4)	22 Sep 2020 16:22:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Sep 2020 16:22:40
Data point term sent to Coder	System	22 Sep 2020 16:21:35
User entered 'hypothyroidism'	Son Do (b) (4)	22 Sep 2020 16:20:56

US3642072

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
User entered 'UN UNK 2017'	Son Do (b) (4)	22 Sep 2020 16:20:56

US3642072

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:12:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
User entered '0'	Son Do (b) (4)	22 Sep 2020 16:20:56

US3642072

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:12:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
User entered 'Yes (Y)'	Son Do (b) (4)	22 Sep 2020 16:20:56

US3642072

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
User entered empty.	Son Do (b) (4)	22 Sep 2020 16:20:56

US3642072

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:12:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
User entered '0'	Son Do (b) (4)	22 Sep 2020 16:20:56

US3642072

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User entered 'Jan 2017'	System	22 Sep 2020 16:20:56

US3642072

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User entered '2017'	System	22 Sep 2020 16:20:56

US3642072

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User entered empty.	System	22 Sep 2020 16:20:56

US3642072

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User entered empty.	System	22 Sep 2020 16:20:56

US3642072

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:12:20

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	22 Sep 2020 16:22:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Sep 2020 16:22:43
Data point term sent to Coder	System	22 Sep 2020 16:21:35
User entered 'hypertension'	Son Do (b) (4)	22 Sep 2020 16:21:10

US3642072

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
User entered 'UN UNK 2017'	Son Do (b) (4)	22 Sep 2020 16:21:10

US3642072

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:12:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
User entered '0'	Son Do (b) (4)	22 Sep 2020 16:21:10

US3642072

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:12:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
User entered 'Yes (Y)'	Son Do (b) (4)	22 Sep 2020 16:21:10

US3642072

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
User entered empty.	Son Do (b) (4)	22 Sep 2020 16:21:10

US3642072

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:12:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
User entered '0'	Son Do (b) (4)	22 Sep 2020 16:21:10

US3642072

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User entered 'Jan 2017'	System	22 Sep 2020 16:21:10

US3642072

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User entered '2017'	System	22 Sep 2020 16:21:10

US3642072

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User entered empty.	System	22 Sep 2020 16:21:10

US3642072

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User entered empty.	System	22 Sep 2020 16:21:10

US3642072

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:12:20

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4)	22 Sep 2020 16:22:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Sep 2020 16:22:43
Data point term sent to Coder	System	22 Sep 2020 16:21:35
User entered 'hyper cholesterol'	Son Do (b) (4)	22 Sep 2020 16:21:33

US3642072

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
User entered 'UN UNK 2017'	Son Do (b) (4)	22 Sep 2020 16:21:33

US3642072

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:12:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
User entered '0'	Son Do (b) (4)	22 Sep 2020 16:21:33

US3642072

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:12:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
User entered 'Yes (Y)'	Son Do (b) (4)	22 Sep 2020 16:21:33

US3642072

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
User entered empty.	Son Do (b) (4)	22 Sep 2020 16:21:33

US3642072

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:12:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
User entered '0'	Son Do (b) (4)	22 Sep 2020 16:21:33

US3642072

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User entered 'Jan 2017'	System	22 Sep 2020 16:21:33

US3642072

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User entered '2017'	System	22 Sep 2020 16:21:33

US3642072

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User entered empty.	System	22 Sep 2020 16:21:33

US3642072

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User entered empty.	System	22 Sep 2020 16:21:33

US3642072

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:12:20

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Bone related signs and symptoms, PT: Bone pain, LLT: Bone pain - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	22 Sep 2020 16:31:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 16:31:37
Data point term sent to Coder	System	22 Sep 2020 16:22:36
User entered 'bone pain (back)'	Son Do (b) (4)	22 Sep 2020 16:21:53

US3642072

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
User entered 'UN UNK 2018'	Son Do (b) (4)	22 Sep 2020 16:21:53

US3642072

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:12:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
User entered '0'	Son Do (b) (4)	22 Sep 2020 16:21:53

US3642072

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:12:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
User entered 'Yes (Y)'	Son Do (b) (4)	22 Sep 2020 16:21:53

US3642072

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
User entered empty.	Son Do (b) (4)	22 Sep 2020 16:21:53

US3642072

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:12:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
User entered '0'	Son Do (b) (4)	22 Sep 2020 16:21:53

US3642072

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User entered 'Jan 2018'	System	22 Sep 2020 16:21:53

US3642072

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User entered '2018'	System	22 Sep 2020 16:21:53

US3642072

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User entered empty.	System	22 Sep 2020 16:21:53

US3642072

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User entered empty.	System	22 Sep 2020 16:21:53

US3642072

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:12:20

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
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)	28 Dec 2020 18:27:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Dec 2020 18:27:22
Data point term sent to Coder	System	28 Dec 2020 18:26:24
User entered 'POST-MENOPAUSAL'	Colleen McLellan (b) (4)	28 Dec 2020 18:25:25

US3642072

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
User entered empty.	(b) (4) Colleen McLellan (b) (4)	28 Dec 2020 18:25:25

US3642072

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:12:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
User entered 'I'	Colleen McLellan (b) (4)	28 Dec 2020 18:25:25

US3642072

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:12:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
User entered 'Yes (Y)'	(b) (4) Colleen McLellan (b) (4)	28 Dec 2020 18:25:25

US3642072

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
User entered empty.	(b) (4) Colleen McLellan (b) (4)	28 Dec 2020 18:25:25

US3642072

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:12:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
User entered '0'	Colleen McLellan (b) (4)	28 Dec 2020 18:25:25

US3642072

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User entered empty.	System	28 Dec 2020 18:25:25

US3642072

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User entered empty.	System	28 Dec 2020 18:25:25

US3642072

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User entered empty.	System	28 Dec 2020 18:25:25

US3642072

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User entered empty.	System	28 Dec 2020 18:25:25

US3642072

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:12:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Yes (Y)'	Son Do (b) (4)	22 Sep 2020 16:25:44

US3642072

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:12:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '01 Sep 2020'	Son Do (b) (4)	22 Sep 2020 16:25:44

US3642072

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '14:51'	Son Do (b) (4)	22 Sep 2020 16:25:44

US3642072

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User entered '01 Sep 2020 14:51'	System	22 Sep 2020 16:25:44

US3642072

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '163' cm	(b) (4)	22 Sep 2020 16:25:44
DataPoint set to visible.	Son Do (b) (4)	01 Sep 2020 23:17:28
	System	

US3642072

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '56.1' kg	(b) (4)	22 Sep 2020 16:25:44
DataPoint set to visible.	Son Do (b) (4)	01 Sep 2020 23:17:28
	System	

US3642072

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:12:20

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User entered '21.11483'	System	22 Sep 2020 16:25:44
DataPoint set to visible.	System	01 Sep 2020 23:17:28

US3642072

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:12:20

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User entered 'kg/m2'	System	22 Sep 2020 16:25:44
DataPoint set to visible.	System	01 Sep 2020 23:17:28

US3642072

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	02 Oct 2020 16:52:39
User entered '98.3' F	Son Do (b) (4)	22 Sep 2020 16:25:44

US3642072

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:12:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered empty; reason for change Data Entry Error	(b) (4)	
	Son Do (b) (4)	02 Oct 2020 16:52:39
User entered 'Oral (Oral)'	Son Do (b) (4)	22 Sep 2020 16:25:44

US3642072

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:12:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered empty.	Son Do (b) (4)	22 Sep 2020 16:25:44

US3642072

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:12:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	02 Oct 2020 16:52:39
User entered '68'	Son Do (b) (4)	22 Sep 2020 16:25:44

US3642072

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:12:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User entered 'bpm'	System	22 Sep 2020 16:25:44

US3642072

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	02 Oct 2020 16:52:39
User entered '18'	Son Do (b) (4)	22 Sep 2020 16:25:44

US3642072

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:12:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User entered 'breaths/min'	System	22 Sep 2020 16:25:44

US3642072

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	02 Oct 2020 16:52:39
User entered '136'	Son Do (b) (4)	22 Sep 2020 16:25:44

US3642072

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:12:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User entered 'mmHg'	System	22 Sep 2020 16:25:44

US3642072

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	02 Oct 2020 16:52:39
User entered '70'	Son Do (b) (4)	22 Sep 2020 16:25:44

US3642072

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:12:20

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User entered 'mmHg'	System	22 Sep 2020 16:25:44

US3642072

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:12:20

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52

US3642072

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:12:20

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52

US3642072

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:12:20

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Yes (Y)'	Son Do (b) (4)	22 Sep 2020 16:24:54

US3642072

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:12:20

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '01 Sep 2020'	Son Do (b) (4)	22 Sep 2020 16:24:54

US3642072

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:12:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '01 Sep 2020'	Son Do (b) (4)	22 Sep 2020 16:27:18

US3642072

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'No (N)'	Son Do (b) (4)	22 Sep 2020 16:27:18

US3642072

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:12:20

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
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) (4), (b) (6)	29 Dec 2020 08:21:48
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 'POST-MENOPAUSAL ADDED TO MEDICAL HISTORY' (Site from DM).	Colleen McLellan (b) (4) (b) (4)	28 Dec 2020 18:24:41
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)	07 Oct 2020 05:42:09
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Son Do (b) (4)	22 Sep 2020 16:27:18

US3642072

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:12:20

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered empty.	Son Do (b) (4)	22 Sep 2020 16:27:18

US3642072

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered empty.	Son Do (b) (4)	22 Sep 2020 16:27:18

US3642072

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:12:20

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '0'	Son Do (b) (4)	22 Sep 2020 16:27:18

US3642072

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered empty.	Son Do (b) (4)	22 Sep 2020 16:27:18

US3642072

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:12:20

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'I'	Son Do (b) (4)	22 Sep 2020 16:27:18

US3642072

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:12:20

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 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Yes (Y)'	Son Do (b) (4)	22 Sep 2020 16:27:41

US3642072

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:12:20

[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 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'No (N)'	Son Do (b) (4)	22 Sep 2020 16:27:41

US3642072

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:12:20

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 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'No (N)'	Son Do (b) (4)	22 Sep 2020 16:27:41

US3642072

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:12:20

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 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'No (N)'	Son Do (b) (4)	22 Sep 2020 16:27:41

US3642072

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:12:20

[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 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'No (N)'	Son Do (b) (4)	22 Sep 2020 16:27:41

US3642072

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:12:20

[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 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'No (N)'	Son Do (b) (4)	22 Sep 2020 16:27:41

US3642072

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:12:20

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 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'No (N)'	Son Do (b) (4)	22 Sep 2020 16:27:41

US3642072

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:12:20

[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 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'No (N)'	Son Do (b) (4)	22 Sep 2020 16:27:41

US3642072

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:12:20

[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 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'No (N)'	Son Do (b) (4)	22 Sep 2020 16:27:41

US3642072

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:12:20

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 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'No (N)'	Son Do (b) (4)	22 Sep 2020 16:27:41

US3642072

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:12:20

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 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'No (N)'	Son Do (b) (4)	22 Sep 2020 16:27:41

US3642072

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:12:20

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'No (N)'	Son Do (b) (4)	22 Sep 2020 16:27:41

US3642072

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:12:20

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered empty.	Son Do (b) (4)	22 Sep 2020 16:27:41

US3642072

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:12:20

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '0'	Son Do (b) (4)	22 Sep 2020 16:27:41

US3642072

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '0'	Son Do (b) (4)	22 Sep 2020 16:27:41

US3642072

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:12:20

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 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '0'	Son Do (b) (4)	22 Sep 2020 16:27:41

US3642072

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:12:20

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 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '0'	Son Do (b) (4)	22 Sep 2020 16:27:41

US3642072

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:12:20

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 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '0'	Son Do (b) (4)	22 Sep 2020 16:27:41

US3642072

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'I'	Son Do (b) (4)	22 Sep 2020 16:27:41

US3642072

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:12:20

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '0'	Son Do (b) (4)	22 Sep 2020 16:27:41

US3642072

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:12:20

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered empty.	Son Do (b) (4)	22 Sep 2020 16:27:41

US3642072

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:12:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Yes (Y)'	(b) (4) Megan Loughran (b) (4)	01 Sep 2020 23:17:45

US3642072

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '1 Sep 2020'	(b) (4) Megan Loughran (b) (4)	01 Sep 2020 23:17:45

US3642072

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Clinic (Clinic)'	(b) (4) Megan Loughran (b) (4)	01 Sep 2020 23:17:45

US3642072

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:12:20

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User entered 'VISIT1'	System	01 Sep 2020 23:17:45

US3642072

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '01 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 22:14:44

US3642072

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '189487'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 22:14:44

US3642072

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 22:14:44

US3642072

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:12:20

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)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'No (N)'	(b) (4) Megan Loughran (b) (4)	01 Sep 2020 23:18:12

US3642072

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:12:20

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)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'No (N)'	(b) (4) Megan Loughran (b) (4)	01 Sep 2020 23:18:12

US3642072

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'No (N)'	(b) (4) Megan Loughran (b) (4)	01 Sep 2020 23:18:12

US3642072

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'No (N)'	(b) (4) Megan Loughran (b) (4)	01 Sep 2020 23:18:12

US3642072

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:12:20

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'No (N)'	(b) (4) Megan Loughran (b) (4)	01 Sep 2020 23:18:12

US3642072

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'No (N)'	Son Do (b) (4)	22 Sep 2020 16:27:50
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 09:03:24
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 09:03:22

US3642072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:12:20

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	02 Oct 2020 16:52:50
User entered '163' cm	Son Do (b) (4)	22 Sep 2020 16:26:36

US3642072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:12:20

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	02 Oct 2020 16:52:50
User entered '56.1' kg	Son Do (b) (4)	22 Sep 2020 16:26:36

US3642072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:12:20

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	02 Oct 2020 16:52:50
User entered '163' cm	Son Do (b) (4)	22 Sep 2020 16:26:36

US3642072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:12:20

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	02 Oct 2020 16:52:50
User entered '56.1' kg	Son Do (b) (4)	22 Sep 2020 16:26:36

US3642072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:12:20

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User accepted default value 'Pre-Dose (PREDOSE)'	Son Do (b) (4)	22 Sep 2020 16:26:36

US3642072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:12:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Yes (Y)'	Son Do (b) (4)	22 Sep 2020 16:26:36

US3642072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:12:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '01 Sep 2020'	Son Do (b) (4)	22 Sep 2020 16:26:36

US3642072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '14:51'	Son Do (b) (4)	22 Sep 2020 16:26:36

US3642072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User entered '01 Sep 2020 14:51'	System	22 Sep 2020 16:26:36

US3642072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:12:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '98.3' F	Son Do (b) (4)	22 Sep 2020 16:26:36

US3642072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:12:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Oral (Oral)'	Son Do (b) (4)	22 Sep 2020 16:26:36

US3642072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:12:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered empty.	Son Do (b) (4)	22 Sep 2020 16:26:36

US3642072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:12:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '68'	Son Do (b) (4)	22 Sep 2020 16:26:36

US3642072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:12:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User entered 'bpm'	System	22 Sep 2020 16:26:36

US3642072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '18'	Son Do (b) (4)	22 Sep 2020 16:26:36

US3642072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:12:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User entered 'breaths/min'	System	22 Sep 2020 16:26:36

US3642072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '136'	Son Do (b) (4)	22 Sep 2020 16:26:36

US3642072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:12:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User entered 'mmHg'	System	22 Sep 2020 16:26:36

US3642072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:12:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '70'	Son Do (b) (4)	22 Sep 2020 16:26:36

US3642072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:12:20

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User entered 'mmHg'	System	22 Sep 2020 16:26:36

US3642072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:12:20

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	02 Oct 2020 16:52:50
User entered '163' cm	Son Do (b) (4)	22 Sep 2020 16:26:36

US3642072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:12:20

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	02 Oct 2020 16:52:50
User entered '56.1' kg	Son Do (b) (4)	22 Sep 2020 16:26:36

US3642072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:12:20

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User accepted default value 'Post-Dose (POSTDOSE)'	Son Do (b) (4)	22 Sep 2020 16:26:36

US3642072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:12:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Yes (Y)'	Son Do (b) (4)	22 Sep 2020 16:26:36

US3642072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:12:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '01 Sep 2020'	Son Do (b) (4)	22 Sep 2020 16:26:36

US3642072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User closed query 'Per CDM: According to Protocol, Post-Dose Vital Signs will be collected at least 30 minutes after IP injection. Treatment time is noted as 16:14, but time of Assessment is 16:43 (29 minutes). Please review and update or provide a clarification. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Dec 2020 10:03:48
Query 'Per CDM: According to Protocol, Post-Dose Vital Signs will be collected at least 30 minutes after IP injection. Treatment time is noted as 16:14, but time of Assessment is 16:43 (29 minutes). Please review and update or provide a clarification. Thank you' answered with 'post-dose VS taken 1 minute early (29 minutes post exposure)' (Site from DM).	Colleen McLellan (b) (4) (b) (4)	14 Dec 2020 20:47:04
User opened query 'Per CDM: According to Protocol, Post-Dose Vital Signs will be collected at least 30 minutes after IP injection. Treatment time is noted as 16:14, but time of Assessment is 16:43 (29 minutes). Please review and update or provide a clarification. Thank you' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 00:32:13
User entered '16:43'	Son Do (b) (4)	22 Sep 2020 16:26:36

US3642072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User entered '01 Sep 2020 16:43'	System	22 Sep 2020 16:26:36

US3642072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:12:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '98.5' F	Son Do (b) (4)	22 Sep 2020 16:26:36

US3642072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:12:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Oral (Oral)'	Son Do (b) (4)	22 Sep 2020 16:26:36

US3642072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:12:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered empty.	Son Do (b) (4)	22 Sep 2020 16:26:36

US3642072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:12:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '65'	Son Do (b) (4)	22 Sep 2020 16:26:36

US3642072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:12:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User entered 'bpm'	System	22 Sep 2020 16:26:36

US3642072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '18'	Son Do (b) (4)	22 Sep 2020 16:26:36

US3642072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:12:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User entered 'breaths/min'	System	22 Sep 2020 16:26:36

US3642072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:12:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '124'	Son Do (b) (4)	22 Sep 2020 16:26:36

US3642072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:12:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User entered 'mmHg'	System	22 Sep 2020 16:26:36

US3642072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:12:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '65'	Son Do (b) (4)	22 Sep 2020 16:26:36

US3642072

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:12:20

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User entered 'mmHg'	System	22 Sep 2020 16:26:36

US3642072

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:12:20

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Son Do	04 Feb 2021 17:08:55
User entered 'Yes (Y)'	Son Do (b) (4)	22 Sep 2020 16:25:04

US3642072

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:12:20

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered empty; reason for change Data Entry Error	(b) (4)	
	Son Do (b) (4)	04 Feb 2021 17:08:55
User entered '01 Sep 2020'	Son Do (b) (4)	22 Sep 2020 16:25:04

US3642072

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:12:20

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Yes (Y)'	(b) (4) Megan Loughran (b) (4)	01 Sep 2020 23:18:57

US3642072

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:12:20

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered empty.	(b) (4) Megan Loughran (b) (4)	01 Sep 2020 23:18:57

US3642072

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered empty.	(b) (4) Megan Loughran (b) (4)	01 Sep 2020 23:18:57

US3642072

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:12:20

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User entered 'MRNA-1273 OR PLACEBO'	System	01 Sep 2020 23:18:57

US3642072

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:12:20

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '1 Sep 2020'	(b) (4) Megan Loughran (b) (4)	01 Sep 2020 23:18:57

US3642072

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '16:14'	(b) (4) Megan Loughran (b) (4)	01 Sep 2020 23:18:57

US3642072

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User entered '1 Sep 2020 16:14'	System	01 Sep 2020 23:18:57

US3642072

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Left Arm (LEFT ARM)'	Megan Loughran (b) (4)	01 Sep 2020 23:18:57

US3642072

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User entered 'ONCE'	System	01 Sep 2020 23:18:57

US3642072

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:12:20

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User entered 'INTRAMUSCULAR'	System	01 Sep 2020 23:18:57

US3642072

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:12:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Yes (Y)'	Son Do (b) (4)	22 Sep 2020 16:26:50

US3642072

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:12:20

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '01 Sep 2020'	Son Do (b) (4)	22 Sep 2020 16:26:50

US3642072

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '15:21'	Son Do (b) (4)	22 Sep 2020 16:26:50

US3642072

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User entered '01 Sep 2020 15:21'	System	22 Sep 2020 16:26:50

US3642072

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:12:20

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '01 Sep 2020'	Son Do (b) (4)	22 Sep 2020 16:27:02

US3642072

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:12:20

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Son Do (b) (4)	22 Sep 2020 16:27:02

US3642072

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:12:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Yes (Y)'	Son Do (b) (4)	22 Sep 2020 16:27:02

US3642072

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:12:20

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '15:25'	Son Do (b) (4)	22 Sep 2020 16:27:02

US3642072

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User entered '01 Sep 2020 15:25'	System	22 Sep 2020 16:27:02

US3642072

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:12:20

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User accepted default value 'Nasopharyngeal Swab 2 Son Do (NASAL2)'	(b) (4)	22 Sep 2020 16:27:02

US3642072

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:12:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'No (N)'	Son Do (b) (4)	22 Sep 2020 16:27:02

US3642072

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered empty.	Son Do (b) (4)	22 Sep 2020 16:27:02

US3642072

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User entered empty.	System	22 Sep 2020 16:27:02

US3642072

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Yes (Y)'	(b) (4) Nancy Tang (b) (4)	10 Sep 2020 21:58:11

US3642072

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:12:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User entered 'I'	System	10 Sep 2020 21:58:11

US3642072

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
Data entry locked.	System	01 Sep 2020 23:18:57
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 23:18:57

US3642072

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:12:20

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-01T16:36:16', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'faaa5ca6-6696-4a45-ad83-73a2c83990a9' User entered 'Yes (Y)'	System	01 Sep 2020 23:36:37
	System	01 Sep 2020 23:36:37

US3642072

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:12:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-01T16:36:23', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'faaa5ca6-6696-4a45-ad83-73a2c83990a9' User entered '98.3'	System	01 Sep 2020 23:36:37
	System	01 Sep 2020 23:36:37

US3642072

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-01T16:36:26', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'faaa5ca6-6696-4a45-ad83-73a2c83990a9' User entered 'No (N)'	System	01 Sep 2020 23:36:37
	System	01 Sep 2020 23:36:37

US3642072

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:12:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-01T16:36:32', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'faaa5ca6-6696-4a45-ad83-73a2c83990a9' User entered '01 Sep 2020 16:36'	System	01 Sep 2020 23:36:37
	System	01 Sep 2020 23:36:37

US3642072

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:12:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '01 Sep 2020 16:34'	System	01 Sep 2020 23:18:57

US3642072

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:12:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '01 Sep 2020 19:04'	System	01 Sep 2020 23:18:57

US3642072

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
Data entry locked.	System	01 Sep 2020 23:18:57
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 23:18:57

US3642072

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:12:20

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-01T20:45:47', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '3029296b-9ecc-4cf6-b4a0-521bb26937bc' User entered 'Yes (Y)'	System	02 Sep 2020 03:46:37
	System	02 Sep 2020 03:46:37

US3642072

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:12:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-01T20:46:15', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '3029296b-9ecc-4cf6-b4a0-521bb26937bc' User entered '98.0'	System	02 Sep 2020 03:46:37
	System	02 Sep 2020 03:46:37

US3642072

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-01T20:46:20', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '3029296b-9ecc-4cf6-b4a0-521bb26937bc' User entered 'No (N)'	System	02 Sep 2020 03:46:37
	System	02 Sep 2020 03:46:37

US3642072

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:12:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-01T20:46:32', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '3029296b-9ecc-4cf6-b4a0-521bb26937bc' User entered '01 Sep 2020 20:46'	System	02 Sep 2020 03:46:37
	System	02 Sep 2020 03:46:37

US3642072

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:12:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '01 Sep 2020 19:59'	System	01 Sep 2020 23:18:57

US3642072

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:12:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 23:18:57

US3642072

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
Data entry locked.	System	01 Sep 2020 23:18:57
User entered 'Day 2'	System	01 Sep 2020 23:18:57

US3642072

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:12:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-02T12:13:49', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '59ea7d8d-46a1-426f-9b45-98c509158c3b' User entered 'Yes (Y)'	System	02 Sep 2020 19:14:20
	System	02 Sep 2020 19:14:20

US3642072

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:12:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-02T12:13:59', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '59ea7d8d-46a1-426f-9b45-98c509158c3b' User entered '97.9'	System	02 Sep 2020 19:14:20
	System	02 Sep 2020 19:14:20

US3642072

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-02T12:14:05', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '59ea7d8d-46a1-426f-9b45-98c509158c3b' User entered 'No (N)'	System	02 Sep 2020 19:14:20
	System	02 Sep 2020 19:14:20

US3642072

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:12:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-02T12:14:16', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '59ea7d8d-46a1-426f-9b45-98c509158c3b' User entered '02 Sep 2020 12:14'	System	02 Sep 2020 19:14:20
	System	02 Sep 2020 19:14:20

US3642072

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:12:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 23:18:57

US3642072

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:12:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 23:18:57

US3642072

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
Data entry locked.	System	01 Sep 2020 23:18:57
User entered 'Day 3'	System	01 Sep 2020 23:18:57

US3642072

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:12:20

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-03T14:13:51', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'f2adae59-839e-41c8-acff-0e9e94e245c3' User entered 'Yes (Y)'	System	03 Sep 2020 21:14:14
	System	03 Sep 2020 21:14:14

US3642072

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:12:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-03T14:14:02', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'f2adae59-839e-41c8-acff-0e9e94e245c3' User entered '96.7'	System	03 Sep 2020 21:14:14
	System	03 Sep 2020 21:14:14

US3642072

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-03T14:14:06', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'f2adae59-839e-41c8-acff-0e9e94e245c3' User entered 'No (N)'	System	03 Sep 2020 21:14:14
	System	03 Sep 2020 21:14:14

US3642072

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:12:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-03T14:14:11', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'f2adae59-839e-41c8-acff-0e9e94e245c3' User entered '03 Sep 2020 14:14'	System	03 Sep 2020 21:14:14
	System	03 Sep 2020 21:14:14

US3642072

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:12:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 23:18:57

US3642072

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:12:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 23:18:57

US3642072

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
Data entry locked.	System	01 Sep 2020 23:18:57
User entered 'Day 4'	System	01 Sep 2020 23:18:57

US3642072

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:12:20

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-04T12:34:58', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'a57e1905-0c86-490a-8299-da1147b4c681' User entered 'Yes (Y)'	System	04 Sep 2020 19:35:30
	System	04 Sep 2020 19:35:30

US3642072

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:12:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-04T12:35:20', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'a57e1905-0c86-490a-8299-da1147b4c681' User entered '96.6'	System	04 Sep 2020 19:35:30
	System	04 Sep 2020 19:35:30

US3642072

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-04T12:35:24', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'a57e1905-0c86-490a-8299-da1147b4c681' User entered 'No (N)'	System	04 Sep 2020 19:35:30
	System	04 Sep 2020 19:35:30

US3642072

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:12:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-04T12:35:28', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'a57e1905-0c86-490a-8299-da1147b4c681' User entered '04 Sep 2020 12:35'	System	04 Sep 2020 19:35:30
	System	04 Sep 2020 19:35:30

US3642072

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:12:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 23:18:57

US3642072

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:12:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 23:18:57

US3642072

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
Data entry locked.	System	01 Sep 2020 23:18:57
User entered 'Day 5'	System	01 Sep 2020 23:18:57

US3642072

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:12:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-05T12:06:33', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'a1070da2-b679-457b-a95e-4c6d68a45b28' User entered 'Yes (Y)'	System	05 Sep 2020 19:06:50
	System	05 Sep 2020 19:06:50

US3642072

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:12:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-05T12:06:40', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'a1070da2-b679-457b-a95e-4c6d68a45b28' User entered '98.2'	System	05 Sep 2020 19:06:50
	System	05 Sep 2020 19:06:50

US3642072

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-05T12:06:44', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'a1070da2-b679-457b-a95e-4c6d68a45b28'	System	05 Sep 2020 19:06:50
User entered 'No (N)'	System	05 Sep 2020 19:06:50

US3642072

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:12:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-05T12:06:48', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'a1070da2-b679-457b-a95e-4c6d68a45b28' User entered '05 Sep 2020 12:06'	System	05 Sep 2020 19:06:50
	System	05 Sep 2020 19:06:50

US3642072

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:12:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 23:18:57

US3642072

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:12:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 23:18:57

US3642072

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
Data entry locked.	System	01 Sep 2020 23:18:57
User entered 'Day 6'	System	01 Sep 2020 23:18:57

US3642072

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:12:20

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-06T12:04:30', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '455fee2b-69f0-4c69-96b3-81c99ff7b682' User entered 'Yes (Y)'	System	06 Sep 2020 19:04:57
	System	06 Sep 2020 19:04:57

US3642072

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:12:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-06T12:04:47', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '455fee2b-69f0-4c69-96b3-81c99ff7b682' User entered '98.5'	System	06 Sep 2020 19:04:57
	System	06 Sep 2020 19:04:57

US3642072

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-06T12:04:51', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '455fee2b-69f0-4c69-96b3-81c99ff7b682'	System	06 Sep 2020 19:04:57
User entered 'No (N)'	System	06 Sep 2020 19:04:57

US3642072

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:12:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-06T12:04:54', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '455fee2b-69f0-4c69-96b3-81c99ff7b682' User entered '06 Sep 2020 12:04'	System	06 Sep 2020 19:04:57
	System	06 Sep 2020 19:04:57

US3642072

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:12:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 23:18:57

US3642072

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:12:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 23:18:57

US3642072

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
Data entry locked.	System	01 Sep 2020 23:18:57
User entered 'Day 7'	System	01 Sep 2020 23:18:57

US3642072

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:12:20

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-07T13:09:36', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'b0af7e41-1e6f-429f-af37-9bab3aa66d7c' User entered 'Yes (Y)'	System	07 Sep 2020 20:09:57
	System	07 Sep 2020 20:09:57

US3642072

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:12:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-07T13:09:44', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'b0af7e41-1e6f-429f-af37-9bab3aa66d7c' User entered '97.6'	System	07 Sep 2020 20:09:57
	System	07 Sep 2020 20:09:57

US3642072

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-07T13:09:48', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'b0af7e41-1e6f-429f-af37-9bab3aa66d7c'	System	07 Sep 2020 20:09:57
User entered 'No (N)'	System	07 Sep 2020 20:09:57

US3642072

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:12:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-07T13:09:53', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'b0af7e41-1e6f-429f-af37-9bab3aa66d7c' User entered '07 Sep 2020 13:09'	System	07 Sep 2020 20:09:57
	System	07 Sep 2020 20:09:57

US3642072

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:12:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 23:18:57

US3642072

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:12:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 23:18:57

US3642072

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
Data entry locked.	System	01 Sep 2020 23:18:57
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 23:18:57

US3642072

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:12:20

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 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-01T16:37:03', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '31c5799c-7ed0-4aa9-8d81-b7d008588853'	System	01 Sep 2020 23:37:27
User entered 'None (1)'	System	01 Sep 2020 23:37:27

US3642072

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:12:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-01T16:37:10', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '31c5799c-7ed0-4aa9-8d81-b7d008588853' User entered 'No (N)'	System	01 Sep 2020 23:37:27
	System	01 Sep 2020 23:37:27

US3642072

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-01T16:37:15', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '31c5799c-7ed0-4aa9-8d81-b7d008588853' User entered 'No (N)'	System	01 Sep 2020 23:37:27
	System	01 Sep 2020 23:37:27

US3642072

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:12:20

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 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-01T16:37:20', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '31c5799c-7ed0-4aa9-8d81-b7d008588853'	System	01 Sep 2020 23:37:27
User entered 'None (1)'	System	01 Sep 2020 23:37:27

US3642072

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:12:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-01T16:37:25', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '31c5799c-7ed0-4aa9-8d81-b7d008588853' User entered '01 Sep 2020 16:37'	System	01 Sep 2020 23:37:27
	System	01 Sep 2020 23:37:27

US3642072

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:12:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '01 Sep 2020 16:34'	System	01 Sep 2020 23:18:57

US3642072

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:12:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '01 Sep 2020 19:04'	System	01 Sep 2020 23:18:57

US3642072

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
Data entry locked.	System	01 Sep 2020 23:18:57
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 23:18:57

US3642072

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:12:20

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 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-01T20:46:44', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'cec129ba-8dee-4f62-bcd8-3e8d8443668e' User entered 'None (1)'	System	02 Sep 2020 03:47:14
	System	02 Sep 2020 03:47:14

US3642072

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:12:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-01T20:46:49', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'cec129ba-8dee-4f62-bcd8-3e8d8443668e' User entered 'No (N)'	System	02 Sep 2020 03:47:14
	System	02 Sep 2020 03:47:14

US3642072

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-01T20:46:53', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'cec129ba-8dee-4f62-bcd8-3e8d8443668e' User entered 'No (N)'	System	02 Sep 2020 03:47:14
	System	02 Sep 2020 03:47:14

US3642072

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:12:20

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 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-01T20:46:59', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'cec129ba-8dee-4f62-bcd8-3e8d8443668e' User entered 'None (1)'	System	02 Sep 2020 03:47:14
	System	02 Sep 2020 03:47:14

US3642072

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:12:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-01T20:47:10', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'cec129ba-8dee-4f62-bcd8-3e8d8443668e' User entered '01 Sep 2020 20:47'	System	02 Sep 2020 03:47:14
	System	02 Sep 2020 03:47:14

US3642072

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:12:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '01 Sep 2020 19:59'	System	01 Sep 2020 23:18:57

US3642072

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:12:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 23:18:57

US3642072

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
Data entry locked.	System	01 Sep 2020 23:18:57
User entered 'Day 2'	System	01 Sep 2020 23:18:57

US3642072

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:12:20

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 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-02T12:14:23', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '37333490-a48b-4138-b151-15b1ca205a15' User entered 'None (1)'	System	02 Sep 2020 19:14:52
	System	02 Sep 2020 19:14:52

US3642072

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:12:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-02T12:14:26', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '37333490-a48b-4138-b151-15b1ca205a15' User entered 'No (N)'	System	02 Sep 2020 19:14:52
	System	02 Sep 2020 19:14:52

US3642072

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-02T12:14:34', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '37333490-a48b-4138-b151-15b1ca205a15' User entered 'No (N)'	System	02 Sep 2020 19:14:52
	System	02 Sep 2020 19:14:52

US3642072

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:12:20

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 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-02T12:14:45', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '37333490-a48b-4138-b151-15b1ca205a15' User entered 'None (1)'	System	02 Sep 2020 19:14:52
	System	02 Sep 2020 19:14:52

US3642072

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:12:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-02T12:14:49', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '37333490-a48b-4138-b151-15b1ca205a15' User entered '02 Sep 2020 12:14'	System	02 Sep 2020 19:14:52
	System	02 Sep 2020 19:14:52

US3642072

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:12:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 23:18:57

US3642072

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:12:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 23:18:57

US3642072

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
Data entry locked.	System	01 Sep 2020 23:18:57
User entered 'Day 3'	System	01 Sep 2020 23:18:57

US3642072

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:12:20

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 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-03T14:14:17', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '7fabfa7f-c2c1-4f8a-a31a-631457998cef' User entered 'None (1)'	System	03 Sep 2020 21:14:34
	System	03 Sep 2020 21:14:34

US3642072

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:12:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-03T14:14:21', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '7fabfa7f-c2c1-4f8a-a31a-631457998cef' User entered 'No (N)'	System	03 Sep 2020 21:14:34
	System	03 Sep 2020 21:14:34

US3642072

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-03T14:14:24', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '7fabfa7f-c2c1-4f8a-a31a-631457998cef' User entered 'No (N)'	System	03 Sep 2020 21:14:34
	System	03 Sep 2020 21:14:34

US3642072

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:12:20

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 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-03T14:14:27', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '7fabfa7f-c2c1-4f8a-a31a-631457998cef' User entered 'None (1)'	System	03 Sep 2020 21:14:34
	System	03 Sep 2020 21:14:34

US3642072

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:12:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-03T14:14:30', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '7fabfa7f-c2c1-4f8a-a31a-631457998cef' User entered '03 Sep 2020 14:14'	System	03 Sep 2020 21:14:34
	System	03 Sep 2020 21:14:34

US3642072

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:12:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 23:18:57

US3642072

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:12:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 23:18:57

US3642072

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
Data entry locked.	System	01 Sep 2020 23:18:57
User entered 'Day 4'	System	01 Sep 2020 23:18:57

US3642072

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:12:20

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 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-04T12:35:33', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'b59ce0bf-e242-422d-8749-100677c981ee' User entered 'None (1)'	System	04 Sep 2020 19:35:50
	System	04 Sep 2020 19:35:50

US3642072

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:12:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-04T12:35:37', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'b59ce0bf-e242-422d-8749-100677c981ee' User entered 'No (N)'	System	04 Sep 2020 19:35:50
	System	04 Sep 2020 19:35:50

US3642072

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-04T12:35:40', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'b59ce0bf-e242-422d-8749-100677c981ee' User entered 'No (N)'	System	04 Sep 2020 19:35:50
	System	04 Sep 2020 19:35:50

US3642072

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:12:20

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 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-04T12:35:44', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'b59ce0bf-e242-422d-8749-100677c981ee' User entered 'None (1)'	System	04 Sep 2020 19:35:50
	System	04 Sep 2020 19:35:50

US3642072

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:12:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-04T12:35:47', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'b59ce0bf-e242-422d-8749-100677c981ee' User entered '04 Sep 2020 12:35'	System	04 Sep 2020 19:35:50
	System	04 Sep 2020 19:35:50

US3642072

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:12:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 23:18:57

US3642072

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:12:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 23:18:57

US3642072

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
Data entry locked.	System	01 Sep 2020 23:18:57
User entered 'Day 5'	System	01 Sep 2020 23:18:57

US3642072

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:12:20

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 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-05T12:06:55', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '77ab9389-33e4-413d-b779-2f1a5c66e428' User entered 'None (1)'	System	05 Sep 2020 19:07:15
	System	05 Sep 2020 19:07:15

US3642072

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-05T12:06:59', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '77ab9389-33e4-413d-b779-2f1a5c66e428' User entered 'No (N)'	System	05 Sep 2020 19:07:15
	System	05 Sep 2020 19:07:15

US3642072

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-05T12:07:02', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '77ab9389-33e4-413d-b779-2f1a5c66e428' User entered 'No (N)'	System	05 Sep 2020 19:07:15
	System	05 Sep 2020 19:07:15

US3642072

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:12:20

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 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-05T12:07:06', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '77ab9389-33e4-413d-b779-2f1a5c66e428' User entered 'None (1)'	System	05 Sep 2020 19:07:15
	System	05 Sep 2020 19:07:15

US3642072

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:12:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-05T12:07:12', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '77ab9389-33e4-413d-b779-2f1a5c66e428' User entered '05 Sep 2020 12:07'	System	05 Sep 2020 19:07:15
	System	05 Sep 2020 19:07:15

US3642072

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:12:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 23:18:57

US3642072

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:12:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 23:18:57

US3642072

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
Data entry locked.	System	01 Sep 2020 23:18:57
User entered 'Day 6'	System	01 Sep 2020 23:18:57

US3642072

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:12:20

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 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-06T12:04:58', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '387f0070-f9b1-4148-b41e-253c11bbbde7' User entered 'None (1)'	System	06 Sep 2020 19:05:13
	System	06 Sep 2020 19:05:13

US3642072

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-06T12:05:01', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '387f0070-f9b1-4148-b41e-253c11bbbde7' User entered 'No (N)'	System	06 Sep 2020 19:05:13
	System	06 Sep 2020 19:05:13

US3642072

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-06T12:05:04', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '387f0070-f9b1-4148-b41e-253c11bbbde7' User entered 'No (N)'	System	06 Sep 2020 19:05:13
	System	06 Sep 2020 19:05:13

US3642072

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:12:20

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 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-06T12:05:08', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '387f0070-f9b1-4148-b41e-253c11bbbde7' User entered 'None (1)'	System	06 Sep 2020 19:05:13
	System	06 Sep 2020 19:05:13

US3642072

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:12:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-06T12:05:11', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '387f0070-f9b1-4148-b41e-253c11bbbde7' User entered '06 Sep 2020 12:05'	System	06 Sep 2020 19:05:13
	System	06 Sep 2020 19:05:13

US3642072

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:12:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 23:18:57

US3642072

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:12:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 23:18:57

US3642072

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
Data entry locked.	System	01 Sep 2020 23:18:57
User entered 'Day 7'	System	01 Sep 2020 23:18:57

US3642072

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:12:20

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 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-07T13:09:58', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '28365d5e-3377-4641-81e5-6c80ff6bcb4f' User entered 'None (1)'	System	07 Sep 2020 20:10:14
	System	07 Sep 2020 20:10:14

US3642072

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:12:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-07T13:10:01', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '28365d5e-3377-4641-81e5-6c80ff6bcb4f' User entered 'No (N)'	System	07 Sep 2020 20:10:14
	System	07 Sep 2020 20:10:14

US3642072

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-07T13:10:04', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '28365d5e-3377-4641-81e5-6c80ff6bcb4f' User entered 'No (N)'	System	07 Sep 2020 20:10:14
	System	07 Sep 2020 20:10:14

US3642072

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:12:20

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 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-07T13:10:07', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '28365d5e-3377-4641-81e5-6c80ff6bcb4f' User entered 'None (1)'	System	07 Sep 2020 20:10:14
	System	07 Sep 2020 20:10:14

US3642072

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:12:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-07T13:10:12', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '28365d5e-3377-4641-81e5-6c80ff6bcb4f' User entered '07 Sep 2020 13:10'	System	07 Sep 2020 20:10:14
	System	07 Sep 2020 20:10:14

US3642072

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:12:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 23:18:57

US3642072

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:12:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 23:18:57

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
Data entry locked.	System	01 Sep 2020 23:18:57
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 23:18:57

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:12:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-01T16:37:30', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'cc0a99b1-cc4a-43ab-b9ea-e07b964069fa' User entered 'None (0)'	System	01 Sep 2020 23:37:54
	System	01 Sep 2020 23:37:54

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:12:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-01T16:37:33', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'cc0a99b1-cc4a-43ab-b9ea-e07b964069fa' User entered 'None (0)'	System	01 Sep 2020 23:37:54
	System	01 Sep 2020 23:37:54

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:12:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-01T16:37:35', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'cc0a99b1-cc4a-43ab-b9ea-e07b964069fa' User entered 'None (0)'	System	01 Sep 2020 23:37:54
	System	01 Sep 2020 23:37:54

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:12:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-01T16:37:38', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'cc0a99b1-cc4a-43ab-b9ea-e07b964069fa' User entered 'None (0)'	System	01 Sep 2020 23:37:54
	System	01 Sep 2020 23:37:54

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:12:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-01T16:37:40', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'cc0a99b1-cc4a-43ab-b9ea-e07b964069fa' User entered 'None (0)'	System	01 Sep 2020 23:37:54
	System	01 Sep 2020 23:37:54

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:12:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-01T16:37:43', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'cc0a99b1-cc4a-43ab-b9ea-e07b964069fa' User entered 'None (0)'	System	01 Sep 2020 23:37:54
	System	01 Sep 2020 23:37:54

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:12:20

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 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-01T16:37:46', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'cc0a99b1-cc4a-43ab-b9ea-e07b964069fa' User entered 'No (N)'	System	01 Sep 2020 23:37:54
	System	01 Sep 2020 23:37:54

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:12:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-01T16:37:49', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'cc0a99b1-cc4a-43ab-b9ea-e07b964069fa' User entered '01 Sep 2020 16:37'	System	01 Sep 2020 23:37:54
	System	01 Sep 2020 23:37:54

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:12:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '01 Sep 2020 16:34'	System	01 Sep 2020 23:18:57

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:12:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '01 Sep 2020 19:04'	System	01 Sep 2020 23:18:57

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
Data entry locked.	System	01 Sep 2020 23:18:57
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 23:18:57

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:12:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-01T20:47:19', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'f65b94f8-ba98-40ed-b59b-9fc3eac955d0' User entered 'None (0)'	System	02 Sep 2020 03:47:49
	System	02 Sep 2020 03:47:49

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:12:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-01T20:47:25', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'f65b94f8-ba98-40ed-b59b-9fc3eac955d0' User entered 'None (0)'	System	02 Sep 2020 03:47:49
	System	02 Sep 2020 03:47:49

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:12:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-01T20:47:28', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'f65b94f8-ba98-40ed-b59b-9fc3eac955d0' User entered 'None (0)'	System	02 Sep 2020 03:47:49
	System	02 Sep 2020 03:47:49

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:12:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-01T20:47:31', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'f65b94f8-ba98-40ed-b59b-9fc3eac955d0' User entered 'None (0)'	System	02 Sep 2020 03:47:49
	System	02 Sep 2020 03:47:49

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:12:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-01T20:47:34', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'f65b94f8-ba98-40ed-b59b-9fc3eac955d0' User entered 'None (0)'	System	02 Sep 2020 03:47:49
	System	02 Sep 2020 03:47:49

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:12:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-01T20:47:37', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'f65b94f8-ba98-40ed-b59b-9fc3eac955d0' User entered 'None (0)'	System	02 Sep 2020 03:47:49
	System	02 Sep 2020 03:47:49

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:12:20

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 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-01T20:47:42', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'f65b94f8-ba98-40ed-b59b-9fc3eac955d0'	System	02 Sep 2020 03:47:49
User entered 'No (N)'	System	02 Sep 2020 03:47:49

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:12:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-01T20:47:46', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'f65b94f8-ba98-40ed-b59b-9fc3eac955d0' User entered '01 Sep 2020 20:47'	System	02 Sep 2020 03:47:49
	System	02 Sep 2020 03:47:49

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:12:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '01 Sep 2020 19:59'	System	01 Sep 2020 23:18:57

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:12:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 23:18:57

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
Data entry locked.	System	01 Sep 2020 23:18:57
User entered 'Day 2'	System	01 Sep 2020 23:18:57

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:12:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-02T12:14:56', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'b023763e-bea8-448d-87f8-500bfefbdf93' User entered 'None (0)'	System	02 Sep 2020 19:15:22
	System	02 Sep 2020 19:15:22

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:12:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-02T12:15:00', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'b023763e-bea8-448d-87f8-500bfefbdf93' User entered 'None (0)'	System	02 Sep 2020 19:15:22
	System	02 Sep 2020 19:15:22

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:12:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-02T12:15:03', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'b023763e-bea8-448d-87f8-500bfefbdf93' User entered 'None (0)'	System	02 Sep 2020 19:15:22
	System	02 Sep 2020 19:15:22

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:12:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-02T12:15:07', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'b023763e-bea8-448d-87f8-500bfefbdf93' User entered 'None (0)'	System	02 Sep 2020 19:15:22
	System	02 Sep 2020 19:15:22

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:12:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-02T12:15:09', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'b023763e-bea8-448d-87f8-500bfefbdf93' User entered 'None (0)'	System	02 Sep 2020 19:15:22
	System	02 Sep 2020 19:15:22

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:12:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-02T12:15:11', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'b023763e-bea8-448d-87f8-500bfefbdf93' User entered 'None (0)'	System	02 Sep 2020 19:15:22
	System	02 Sep 2020 19:15:22

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:12:20

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 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-02T12:15:16', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'b023763e-bea8-448d-87f8-500bfefbdf93' User entered 'No (N)'	System	02 Sep 2020 19:15:22
	System	02 Sep 2020 19:15:22

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:12:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-02T12:15:20', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'b023763e-bea8-448d-87f8-500bfefbdf93' User entered '02 Sep 2020 12:15'	System	02 Sep 2020 19:15:22
	System	02 Sep 2020 19:15:22

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:12:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 23:18:57

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:12:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 23:18:57

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
Data entry locked.	System	01 Sep 2020 23:18:57
User entered 'Day 3'	System	01 Sep 2020 23:18:57

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:12:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-03T14:14:35', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'fd6f4145-61ff-4423-bc7e-8dbe3f564330' User entered 'None (0)'	System	03 Sep 2020 21:14:54
	System	03 Sep 2020 21:14:54

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:12:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-03T14:14:37', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'fd6f4145-61ff-4423-bc7e-8dbe3f564330' User entered 'None (0)'	System	03 Sep 2020 21:14:54
	System	03 Sep 2020 21:14:54

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:12:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-03T14:14:40', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'fd6f4145-61ff-4423-bc7e-8dbe3f564330' User entered 'None (0)'	System	03 Sep 2020 21:14:54
	System	03 Sep 2020 21:14:54

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:12:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-03T14:14:42', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'fd6f4145-61ff-4423-bc7e-8dbe3f564330' User entered 'None (0)'	System	03 Sep 2020 21:14:54
	System	03 Sep 2020 21:14:54

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:12:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-03T14:14:44', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'fd6f4145-61ff-4423-bc7e-8dbe3f564330' User entered 'None (0)'	System	03 Sep 2020 21:14:54
	System	03 Sep 2020 21:14:54

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:12:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-03T14:14:46', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'fd6f4145-61ff-4423-bc7e-8dbe3f564330' User entered 'None (0)'	System	03 Sep 2020 21:14:54
	System	03 Sep 2020 21:14:54

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:12:20

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 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-03T14:14:49', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'fd6f4145-61ff-4423-bc7e-8dbe3f564330' User entered 'No (N)'	System	03 Sep 2020 21:14:54
	System	03 Sep 2020 21:14:54

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:12:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-03T14:14:52', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'fd6f4145-61ff-4423-bc7e-8dbe3f564330' User entered '03 Sep 2020 14:14'	System	03 Sep 2020 21:14:54
	System	03 Sep 2020 21:14:54

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:12:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 23:18:57

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:12:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 23:18:57

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
Data entry locked.	System	01 Sep 2020 23:18:57
User entered 'Day 4'	System	01 Sep 2020 23:18:57

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:12:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-04T12:35:53', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'a666c658-8442-4312-b4e8-06b2b8cf3c09' User entered 'None (0)'	System	04 Sep 2020 19:36:17
	System	04 Sep 2020 19:36:17

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:12:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-04T12:35:56', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'a666c658-8442-4312-b4e8-06b2b8cf3c09' User entered 'None (0)'	System	04 Sep 2020 19:36:17
	System	04 Sep 2020 19:36:17

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:12:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-04T12:35:58', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'a666c658-8442-4312-b4e8-06b2b8cf3c09' User entered 'None (0)'	System	04 Sep 2020 19:36:17
	System	04 Sep 2020 19:36:17

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:12:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-04T12:36:01', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'a666c658-8442-4312-b4e8-06b2b8cf3c09' User entered 'None (0)'	System	04 Sep 2020 19:36:17
	System	04 Sep 2020 19:36:17

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:12:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-04T12:36:04', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'a666c658-8442-4312-b4e8-06b2b8cf3c09' User entered 'None (0)'	System	04 Sep 2020 19:36:17
	System	04 Sep 2020 19:36:17

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:12:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-04T12:36:07', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'a666c658-8442-4312-b4e8-06b2b8cf3c09' User entered 'None (0)'	System	04 Sep 2020 19:36:17
	System	04 Sep 2020 19:36:17

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:12:20

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 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-04T12:36:11', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'a666c658-8442-4312-b4e8-06b2b8cf3c09' User entered 'No (N)'	System	04 Sep 2020 19:36:17
	System	04 Sep 2020 19:36:17

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:12:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-04T12:36:14', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'a666c658-8442-4312-b4e8-06b2b8cf3c09' User entered '04 Sep 2020 12:36'	System	04 Sep 2020 19:36:17
	System	04 Sep 2020 19:36:17

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:12:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 23:18:57

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:12:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 23:18:57

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
Data entry locked.	System	01 Sep 2020 23:18:57
User entered 'Day 5'	System	01 Sep 2020 23:18:57

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:12:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-05T12:07:17', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '96587f0e-f05e-47f9-ab4e-6d78608e76b0' User entered 'None (0)'	System	05 Sep 2020 19:07:40
	System	05 Sep 2020 19:07:40

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:12:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-05T12:07:19', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '96587f0e-f05e-47f9-ab4e-6d78608e76b0' User entered 'None (0)'	System	05 Sep 2020 19:07:40
	System	05 Sep 2020 19:07:40

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:12:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-05T12:07:23', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '96587f0e-f05e-47f9-ab4e-6d78608e76b0' User entered 'None (0)'	System	05 Sep 2020 19:07:40
	System	05 Sep 2020 19:07:40

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:12:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-05T12:07:26', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '96587f0e-f05e-47f9-ab4e-6d78608e76b0' User entered 'None (0)'	System	05 Sep 2020 19:07:40
	System	05 Sep 2020 19:07:40

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:12:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-05T12:07:28', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '96587f0e-f05e-47f9-ab4e-6d78608e76b0' User entered 'None (0)'	System	05 Sep 2020 19:07:40
	System	05 Sep 2020 19:07:40

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:12:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-05T12:07:31', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '96587f0e-f05e-47f9-ab4e-6d78608e76b0' User entered 'None (0)'	System	05 Sep 2020 19:07:40
	System	05 Sep 2020 19:07:40

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:12:20

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 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-05T12:07:35', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '96587f0e-f05e-47f9-ab4e-6d78608e76b0' User entered 'No (N)'	System	05 Sep 2020 19:07:40
	System	05 Sep 2020 19:07:40

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:12:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-05T12:07:38', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '96587f0e-f05e-47f9-ab4e-6d78608e76b0' User entered '05 Sep 2020 12:07'	System	05 Sep 2020 19:07:40
	System	05 Sep 2020 19:07:40

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:12:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 23:18:57

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:12:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 23:18:57

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
Data entry locked.	System	01 Sep 2020 23:18:57
User entered 'Day 6'	System	01 Sep 2020 23:18:57

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:12:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-06T12:05:17', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'fa2b5cc5-21f1-4626-8e99-c98cd1e819f1' User entered 'None (0)'	System	06 Sep 2020 19:05:44
	System	06 Sep 2020 19:05:44

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:12:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-06T12:05:20', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'fa2b5cc5-21f1-4626-8e99-c98cd1e819f1' User entered 'None (0)'	System	06 Sep 2020 19:05:44
	System	06 Sep 2020 19:05:44

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:12:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-06T12:05:24', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'fa2b5cc5-21f1-4626-8e99-c98cd1e819f1' User entered 'None (0)'	System	06 Sep 2020 19:05:44
	System	06 Sep 2020 19:05:44

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:12:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-06T12:05:26', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'fa2b5cc5-21f1-4626-8e99-c98cd1e819f1' User entered 'None (0)'	System	06 Sep 2020 19:05:44
	System	06 Sep 2020 19:05:44

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:12:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-06T12:05:30', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'fa2b5cc5-21f1-4626-8e99-c98cd1e819f1' User entered 'None (0)'	System	06 Sep 2020 19:05:44
	System	06 Sep 2020 19:05:44

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:12:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-06T12:05:32', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'fa2b5cc5-21f1-4626-8e99-c98cd1e819f1' User entered 'None (0)'	System	06 Sep 2020 19:05:44
	System	06 Sep 2020 19:05:44

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:12:20

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 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-06T12:05:36', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'fa2b5cc5-21f1-4626-8e99-c98cd1e819f1' User entered 'No (N)'	System	06 Sep 2020 19:05:44
	System	06 Sep 2020 19:05:44

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:12:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-06T12:05:41', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'fa2b5cc5-21f1-4626-8e99-c98cd1e819f1' User entered '06 Sep 2020 12:05'	System	06 Sep 2020 19:05:44
	System	06 Sep 2020 19:05:44

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:12:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 23:18:57

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:12:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 23:18:57

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
Data entry locked.	System	01 Sep 2020 23:18:57
User entered 'Day 7'	System	01 Sep 2020 23:18:57

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:12:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-07T13:10:17', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '97ba2be5-99a7-4f73-a903-2e17b284ea13' User entered 'None (0)'	System	07 Sep 2020 20:10:37
	System	07 Sep 2020 20:10:37

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:12:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-07T13:10:19', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '97ba2be5-99a7-4f73-a903-2e17b284ea13' User entered 'None (0)'	System	07 Sep 2020 20:10:37
	System	07 Sep 2020 20:10:37

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:12:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-07T13:10:21', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '97ba2be5-99a7-4f73-a903-2e17b284ea13' User entered 'None (0)'	System	07 Sep 2020 20:10:37
	System	07 Sep 2020 20:10:37

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:12:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-07T13:10:24', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '97ba2be5-99a7-4f73-a903-2e17b284ea13' User entered 'None (0)'	System	07 Sep 2020 20:10:37
	System	07 Sep 2020 20:10:37

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:12:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-07T13:10:26', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '97ba2be5-99a7-4f73-a903-2e17b284ea13' User entered 'None (0)'	System	07 Sep 2020 20:10:37
	System	07 Sep 2020 20:10:37

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:12:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-07T13:10:29', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '97ba2be5-99a7-4f73-a903-2e17b284ea13' User entered 'None (0)'	System	07 Sep 2020 20:10:37
	System	07 Sep 2020 20:10:37

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:12:20

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 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-07T13:10:32', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '97ba2be5-99a7-4f73-a903-2e17b284ea13' User entered 'No (N)'	System	07 Sep 2020 20:10:37
	System	07 Sep 2020 20:10:37

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:12:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-07T13:10:34', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '97ba2be5-99a7-4f73-a903-2e17b284ea13' User entered '07 Sep 2020 13:10'	System	07 Sep 2020 20:10:37
	System	07 Sep 2020 20:10:37

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:12:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 23:18:57

US3642072

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:12:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 23:18:57

US3642072

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:12:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Yes (Y)'	(b) (4) Nancy Tang (b) (4)	10 Sep 2020 21:58:56

US3642072

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:12:20

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '10 Sep 2020'	(b) (4) Nancy Tang (b) (4)	10 Sep 2020 21:58:56

US3642072

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:12:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Nancy Tang (b) (4)	10 Sep 2020 21:58:56

US3642072

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:12:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered empty.	(b) (4) Nancy Tang (b) (4)	10 Sep 2020 21:58:56

US3642072

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Yes (Y)'	(b) (4) Nancy Tang (b) (4)	10 Sep 2020 21:59:02

US3642072

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:12:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User entered 'I'	System	10 Sep 2020 21:59:02

US3642072

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:12:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:56:21

US3642072

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:12:20

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '17 Sep 2020'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:56:21

US3642072

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:12:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:56:21

US3642072

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:12:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:56:21

US3642072

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:56:28

US3642072

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:12:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User entered 'I'	System	17 Sep 2020 20:56:28

US3642072

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:12:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Yes (Y)'	(b) (4) Colleen McLellan (b) (4)	23 Sep 2020 20:55:20

US3642072

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:12:20

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '23 Sep 2020'	Colleen McLellan (b) (4)	23 Sep 2020 20:55:20

US3642072

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:12:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Contact Made (CONTACT MADE)'	Colleen McLellan (b) (4)	23 Sep 2020 20:55:20

US3642072

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:12:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered empty.	Colleen McLellan (b) (4)	23 Sep 2020 20:55:20

US3642072

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Yes (Y)'	(b) (4) Colleen McLellan (b) (4)	23 Sep 2020 20:55:26

US3642072

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:12:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User entered 'I'	System	23 Sep 2020 20:55:26

US3642072

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:12:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Yes (Y)'	(b) (4) Megan Loughran (b) (4)	29 Sep 2020 21:46:03

US3642072

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '29 Sep 2020'	(b) (4) Megan Loughran (b) (4)	29 Sep 2020 21:46:03

US3642072

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Clinic (Clinic)'	(b) (4) Megan Loughran (b) (4)	29 Sep 2020 21:46:03

US3642072

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:12:20

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User entered 'VISIT2'	System	29 Sep 2020 21:46:03

US3642072

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:12:20

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User accepted default value 'Pre-Dose (PREDOSE)'	Son Do (b) (4)	02 Oct 2020 16:43:42

US3642072

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:12:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Yes (Y)'	Son Do (b) (4)	02 Oct 2020 16:43:42

US3642072

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:12:20

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '29 Sep 2020'	Son Do (b) (4)	02 Oct 2020 16:43:42

US3642072

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '14:26'	Son Do (b) (4)	02 Oct 2020 16:43:42

US3642072

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User entered '29 Sep 2020 14:26'	System	02 Oct 2020 16:43:42

US3642072

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:12:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '98.4' F	Son Do (b) (4)	02 Oct 2020 16:43:42

US3642072

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:12:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Oral (Oral)'	Son Do (b) (4)	02 Oct 2020 16:43:42

US3642072

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:12:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered empty.	Son Do (b) (4)	02 Oct 2020 16:43:42

US3642072

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:12:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '64'	Son Do (b) (4)	02 Oct 2020 16:43:42

US3642072

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:12:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User entered 'bpm'	System	02 Oct 2020 16:43:42

US3642072

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '14'	Son Do (b) (4)	02 Oct 2020 16:43:42

US3642072

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:12:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User entered 'breaths/min'	System	02 Oct 2020 16:43:42

US3642072

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '112'	Son Do (b) (4)	02 Oct 2020 16:43:42

US3642072

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:12:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User entered 'mmHg'	System	02 Oct 2020 16:43:42

US3642072

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '65'	Son Do (b) (4)	02 Oct 2020 16:43:42

US3642072

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:12:20

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User entered 'mmHg'	System	02 Oct 2020 16:43:42

US3642072

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:12:20

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User accepted default value 'Post-Dose (POSTDOSE)'	Son Do (b) (4)	02 Oct 2020 16:43:42

US3642072

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:12:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Yes (Y)'	Son Do (b) (4)	02 Oct 2020 16:43:42

US3642072

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:12:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '29 Sep 2020'	Son Do (b) (4)	02 Oct 2020 16:43:42

US3642072

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '16:32'	Son Do (b) (4)	02 Oct 2020 16:43:42

US3642072

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User entered '29 Sep 2020 16:32'	System	02 Oct 2020 16:43:42

US3642072

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:12:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '98.1' F	Son Do (b) (4)	02 Oct 2020 16:43:42

US3642072

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:12:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Oral (Oral)'	Son Do (b) (4)	02 Oct 2020 16:43:42

US3642072

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:12:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered empty.	Son Do (b) (4)	02 Oct 2020 16:43:42

US3642072

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:12:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '61'	Son Do (b) (4)	02 Oct 2020 16:43:42

US3642072

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:12:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User entered 'bpm'	System	02 Oct 2020 16:43:42

US3642072

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '16'	Son Do (b) (4)	02 Oct 2020 16:43:42

US3642072

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:12:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User entered 'breaths/min'	System	02 Oct 2020 16:43:42

US3642072

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '125'	Son Do (b) (4)	02 Oct 2020 16:43:42

US3642072

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:12:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User entered 'mmHg'	System	02 Oct 2020 16:43:42

US3642072

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:12:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '71'	Son Do (b) (4)	02 Oct 2020 16:43:42

US3642072

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:12:20

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User entered 'mmHg'	System	02 Oct 2020 16:43:42

US3642072

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:12:20

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Yes (Y)'	Son Do (b) (4)	02 Oct 2020 16:43:50

US3642072

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:12:20

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '29 Sep 2020'	Son Do (b) (4)	02 Oct 2020 16:43:50

US3642072

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:12:20

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 23:01:48

US3642072

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:12:20

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 23:01:48

US3642072

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 23:01:48

US3642072

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:12:20

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User entered 'MRNA-1273 OR PLACEBO'	System	29 Sep 2020 23:01:48

US3642072

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:12:20

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '29 Sep 2020'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 23:01:48

US3642072

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '15:59'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 23:01:48

US3642072

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User entered '29 Sep 2020 15:59'	System	29 Sep 2020 23:01:48

US3642072

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 23:01:48

US3642072

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User entered 'ONCE'	System	29 Sep 2020 23:01:48

US3642072

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:12:20

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User entered 'INTRAMUSCULAR'	System	29 Sep 2020 23:01:48

US3642072

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:12:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Yes (Y)'	Son Do (b) (4)	02 Oct 2020 16:44:01

US3642072

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:12:20

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '29 Sep 2020'	Son Do (b) (4)	02 Oct 2020 16:44:01

US3642072

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:12:20

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '15:00'	Son Do (b) (4)	02 Oct 2020 16:44:01

US3642072

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User entered '29 Sep 2020 15:00'	System	02 Oct 2020 16:44:01

US3642072

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:12:20

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '29 Sep 2020'	Son Do (b) (4)	02 Oct 2020 16:44:14

US3642072

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:12:20

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Son Do (b) (4)	02 Oct 2020 16:44:14

US3642072

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:12:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Yes (Y)'	Son Do (b) (4)	02 Oct 2020 16:44:14

US3642072

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:12:20

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '15:03'	Son Do (b) (4)	02 Oct 2020 16:44:14

US3642072

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User entered '29 Sep 2020 15:03'	System	02 Oct 2020 16:44:14

US3642072

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:12:20

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User accepted default value 'Nasopharyngeal Swab 2 Son Do (NASAL2)'	(b) (4)	02 Oct 2020 16:44:14

US3642072

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:12:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'No (N)'	Son Do (b) (4)	02 Oct 2020 16:44:14

US3642072

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:12:20

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered empty.	Son Do (b) (4)	02 Oct 2020 16:44:14

US3642072

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User entered empty.	System	02 Oct 2020 16:44:14

US3642072

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Yes (Y)'	Son Do (b) (4)	02 Oct 2020 16:44:20

US3642072

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:12:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User entered 'I'	System	02 Oct 2020 16:44:20

US3642072

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
Data entry locked.	System	29 Sep 2020 23:01:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 23:01:48

US3642072

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:12:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-29T16:19:46', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'f8f51d72-771b-4d0a-8792-b82850346da8' User entered 'Yes (Y)'	System	29 Sep 2020 23:20:34
	System	29 Sep 2020 23:20:34

US3642072

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:12:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-29T16:20:24', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'f8f51d72-771b-4d0a-8792-b82850346da8' User entered '98.1'	System	29 Sep 2020 23:20:34
	System	29 Sep 2020 23:20:34

US3642072

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-29T16:20:27', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'f8f51d72-771b-4d0a-8792-b82850346da8' User entered 'No (N)'	System	29 Sep 2020 23:20:34
	System	29 Sep 2020 23:20:34

US3642072

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:12:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-29T16:20:32', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'f8f51d72-771b-4d0a-8792-b82850346da8' User entered '29 Sep 2020 16:20'	System	29 Sep 2020 23:20:34
	System	29 Sep 2020 23:20:34

US3642072

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:12:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '29 Sep 2020 16:19'	System	29 Sep 2020 23:01:48

US3642072

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:12:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '29 Sep 2020 18:49'	System	29 Sep 2020 23:01:48

US3642072

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
Data entry locked.	System	29 Sep 2020 23:01:48
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 23:01:48

US3642072

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:12:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-29T19:56:58', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '10806a42-0035-4399-a284-55d8c064fdf8' User entered 'Yes (Y)'	System	30 Sep 2020 02:57:21
	System	30 Sep 2020 02:57:21

US3642072

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:12:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-29T19:57:07', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '10806a42-0035-4399-a284-55d8c064fdf8' User entered '96.9'	System	30 Sep 2020 02:57:21
	System	30 Sep 2020 02:57:21

US3642072

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-29T19:57:11', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '10806a42-0035-4399-a284-55d8c064fdf8' User entered 'No (N)'	System	30 Sep 2020 02:57:21
	System	30 Sep 2020 02:57:21

US3642072

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:12:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-29T19:57:17', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '10806a42-0035-4399-a284-55d8c064fdf8' User entered '29 Sep 2020 19:57'	System	30 Sep 2020 02:57:21
	System	30 Sep 2020 02:57:21

US3642072

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:12:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '29 Sep 2020 19:44'	System	29 Sep 2020 23:01:48

US3642072

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:12:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 23:01:48

US3642072

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
Data entry locked.	System	29 Sep 2020 23:01:48
User entered 'Day 2'	System	29 Sep 2020 23:01:48

US3642072

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:12:20

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-30T15:29:35', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '3ca9f4b1-7d0c-4741-bcec-8b9a05702a6b' User entered 'Yes (Y)'	System	30 Sep 2020 22:29:53
	System	30 Sep 2020 22:29:53

US3642072

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:12:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-30T15:29:42', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '3ca9f4b1-7d0c-4741-bcec-8b9a05702a6b' User entered '98.3'	System	30 Sep 2020 22:29:53
	System	30 Sep 2020 22:29:53

US3642072

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-30T15:29:46', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '3ca9f4b1-7d0c-4741-bcec-8b9a05702a6b' User entered 'No (N)'	System	30 Sep 2020 22:29:53
	System	30 Sep 2020 22:29:53

US3642072

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:12:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-30T15:29:51', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '3ca9f4b1-7d0c-4741-bcec-8b9a05702a6b' User entered '30 Sep 2020 15:29'	System	30 Sep 2020 22:29:53
	System	30 Sep 2020 22:29:53

US3642072

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:12:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 23:01:48

US3642072

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:12:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 23:01:48

US3642072

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
Data entry locked.	System	29 Sep 2020 23:01:48
User entered 'Day 3'	System	29 Sep 2020 23:01:48

US3642072

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:12:20

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-01T13:31:24', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'e4902c7c-801d-4b84-8f2f-59bcfee41a1b' User entered 'Yes (Y)'	System	01 Oct 2020 20:31:41
	System	01 Oct 2020 20:31:41

US3642072

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:12:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-01T13:31:30', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'e4902c7c-801d-4b84-8f2f-59bcfee41a1b' User entered '96.1'	System	01 Oct 2020 20:31:41
	System	01 Oct 2020 20:31:41

US3642072

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-01T13:31:33', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'e4902c7c-801d-4b84-8f2f-59bcfee41a1b'	System	01 Oct 2020 20:31:41
User entered 'No (N)'	System	01 Oct 2020 20:31:41

US3642072

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:12:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-01T13:31:37', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'e4902c7c-801d-4b84-8f2f-59bcfee41a1b' User entered '01 Oct 2020 13:31'	System	01 Oct 2020 20:31:41
	System	01 Oct 2020 20:31:41

US3642072

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:12:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 23:01:48

US3642072

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:12:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 23:01:48

US3642072

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
Data entry locked.	System	29 Sep 2020 23:01:48
User entered 'Day 4'	System	29 Sep 2020 23:01:48

US3642072

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:12:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-02T14:27:37', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '570ddca3-d6b1-47c9-8030-0e125a328e03' User entered 'Yes (Y)'	System	02 Oct 2020 21:27:52
	System	02 Oct 2020 21:27:52

US3642072

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:12:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-02T14:27:43', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '570ddca3-d6b1-47c9-8030-0e125a328e03' User entered '97.1'	System	02 Oct 2020 21:27:52
	System	02 Oct 2020 21:27:52

US3642072

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-02T14:27:46', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '570ddca3-d6b1-47c9-8030-0e125a328e03' User entered 'No (N)'	System	02 Oct 2020 21:27:52
	System	02 Oct 2020 21:27:52

US3642072

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:12:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-02T14:27:50', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '570ddca3-d6b1-47c9-8030-0e125a328e03' User entered '02 Oct 2020 14:27'	System	02 Oct 2020 21:27:52
	System	02 Oct 2020 21:27:52

US3642072

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:12:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 23:01:48

US3642072

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:12:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 23:01:48

US3642072

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
Data entry locked.	System	29 Sep 2020 23:01:48
User entered 'Day 5'	System	29 Sep 2020 23:01:48

US3642072

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:12:20

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-03T16:30:03', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '642fcffa-8d9b-44a9-8e6f-3d72d242575b' User entered 'Yes (Y)'	System	03 Oct 2020 23:30:18
	System	03 Oct 2020 23:30:18

US3642072

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:12:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-03T16:30:09', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '642fcffa-8d9b-44a9-8e6f-3d72d242575b' User entered '97.7'	System	03 Oct 2020 23:30:18
	System	03 Oct 2020 23:30:18

US3642072

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-03T16:30:13', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '642fcffa-8d9b-44a9-8e6f-3d72d242575b' User entered 'No (N)'	System	03 Oct 2020 23:30:18
	System	03 Oct 2020 23:30:18

US3642072

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:12:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-03T16:30:17', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '642fcffa-8d9b-44a9-8e6f-3d72d242575b' User entered '03 Oct 2020 16:30'	System	03 Oct 2020 23:30:18
	System	03 Oct 2020 23:30:18

US3642072

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:12:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 23:01:48

US3642072

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:12:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 23:01:48

US3642072

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
Data entry locked.	System	29 Sep 2020 23:01:48
User entered 'Day 6'	System	29 Sep 2020 23:01:48

US3642072

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:12:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-04T14:59:49', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'fdd7c535-f9fe-4cc1-a6ea-0a0cc9a4d175' User entered 'Yes (Y)'	System	04 Oct 2020 22:00:09
	System	04 Oct 2020 22:00:09

US3642072

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:12:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-04T14:59:55', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'fdd7c535-f9fe-4cc1-a6ea-0a0cc9a4d175' User entered '98.3'	System	04 Oct 2020 22:00:09
	System	04 Oct 2020 22:00:09

US3642072

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-04T14:59:58', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'fdd7c535-f9fe-4cc1-a6ea-0a0cc9a4d175'	System	04 Oct 2020 22:00:09
User entered 'No (N)'	System	04 Oct 2020 22:00:09

US3642072

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:12:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-04T15:00:03', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'fdd7c535-f9fe-4cc1-a6ea-0a0cc9a4d175' User entered '04 Oct 2020 15:00'	System	04 Oct 2020 22:00:09
	System	04 Oct 2020 22:00:09

US3642072

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:12:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 23:01:48

US3642072

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:12:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 23:01:48

US3642072

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
Data entry locked.	System	29 Sep 2020 23:01:48
User entered 'Day 7'	System	29 Sep 2020 23:01:48

US3642072

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:12:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-05T14:55:19', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '25c06ee7-1bcd-47a0-add4-400a57418e44' User entered 'Yes (Y)'	System	05 Oct 2020 21:55:38
	System	05 Oct 2020 21:55:38

US3642072

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:12:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-05T14:55:26', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '25c06ee7-1bcd-47a0-add4-400a57418e44' User entered '97.9'	System	05 Oct 2020 21:55:38
	System	05 Oct 2020 21:55:38

US3642072

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-05T14:55:30', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '25c06ee7-1bcd-47a0-add4-400a57418e44'	System	05 Oct 2020 21:55:38
User entered 'No (N)'	System	05 Oct 2020 21:55:38

US3642072

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:12:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-05T14:55:36', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '25c06ee7-1bcd-47a0-add4-400a57418e44' User entered '05 Oct 2020 14:55'	System	05 Oct 2020 21:55:38
	System	05 Oct 2020 21:55:38

US3642072

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:12:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 23:01:48

US3642072

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:12:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 23:01:48

US3642072

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
Data entry locked.	System	29 Sep 2020 23:01:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 23:01:48

US3642072

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:12:20

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 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-29T16:21:05', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '6c5467f6-818c-48c3-9a5d-11eb315f26dd' User entered 'None (1)'	System	29 Sep 2020 23:21:24
	System	29 Sep 2020 23:21:24

US3642072

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:12:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-29T16:21:08', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '6c5467f6-818c-48c3-9a5d-11eb315f26dd' User entered 'No (N)'	System	29 Sep 2020 23:21:24
	System	29 Sep 2020 23:21:24

US3642072

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-29T16:21:10', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '6c5467f6-818c-48c3-9a5d-11eb315f26dd' User entered 'No (N)'	System	29 Sep 2020 23:21:24
	System	29 Sep 2020 23:21:24

US3642072

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:12:20

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 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-29T16:21:16', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '6c5467f6-818c-48c3-9a5d-11eb315f26dd' User entered 'None (1)'	System	29 Sep 2020 23:21:24
	System	29 Sep 2020 23:21:24

US3642072

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:12:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-29T16:21:20', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '6c5467f6-818c-48c3-9a5d-11eb315f26dd' User entered '29 Sep 2020 16:21'	System	29 Sep 2020 23:21:24
	System	29 Sep 2020 23:21:24

US3642072

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:12:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '29 Sep 2020 16:19'	System	29 Sep 2020 23:01:48

US3642072

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:12:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '29 Sep 2020 18:49'	System	29 Sep 2020 23:01:48

US3642072

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
Data entry locked.	System	29 Sep 2020 23:01:48
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 23:01:48

US3642072

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:12:20

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 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-29T19:57:27', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '9492cfce-665b-42cc-ad4f-8f4880459d7a' User entered 'None (1)'	System	30 Sep 2020 02:57:49
	System	30 Sep 2020 02:57:49

US3642072

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:12:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-29T19:57:31', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '9492cfce-665b-42cc-ad4f-8f4880459d7a' User entered 'No (N)'	System	30 Sep 2020 02:57:49
	System	30 Sep 2020 02:57:49

US3642072

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-29T19:57:34', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '9492cfce-665b-42cc-ad4f-8f4880459d7a' User entered 'No (N)'	System	30 Sep 2020 02:57:49
	System	30 Sep 2020 02:57:49

US3642072

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:12:20

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 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-29T19:57:39', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '9492cfce-665b-42cc-ad4f-8f4880459d7a' User entered 'None (1)'	System	30 Sep 2020 02:57:49
	System	30 Sep 2020 02:57:49

US3642072

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:12:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-29T19:57:45', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '9492cfce-665b-42cc-ad4f-8f4880459d7a' User entered '29 Sep 2020 19:57'	System	30 Sep 2020 02:57:49
	System	30 Sep 2020 02:57:49

US3642072

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:12:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '29 Sep 2020 19:44'	System	29 Sep 2020 23:01:48

US3642072

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:12:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 23:01:48

US3642072

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
Data entry locked.	System	29 Sep 2020 23:01:48
User entered 'Day 2'	System	29 Sep 2020 23:01:48

US3642072

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:12:20

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 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-30T15:29:57', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '5723d296-60e7-42a5-ae1c-58357ace81cf' User entered 'None (1)'	System	30 Sep 2020 22:30:17
	System	30 Sep 2020 22:30:17

US3642072

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:12:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-30T15:30:02', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '5723d296-60e7-42a5-ae1c-58357ace81cf' User entered 'No (N)'	System	30 Sep 2020 22:30:17
	System	30 Sep 2020 22:30:17

US3642072

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-30T15:30:08', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '5723d296-60e7-42a5-ae1c-58357ace81cf' User entered 'No (N)'	System	30 Sep 2020 22:30:17
	System	30 Sep 2020 22:30:17

US3642072

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:12:20

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 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-30T15:30:12', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '5723d296-60e7-42a5-ae1c-58357ace81cf' User entered 'None (1)'	System	30 Sep 2020 22:30:17
	System	30 Sep 2020 22:30:17

US3642072

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:12:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-30T15:30:15', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '5723d296-60e7-42a5-ae1c-58357ace81cf' User entered '30 Sep 2020 15:30'	System	30 Sep 2020 22:30:17
	System	30 Sep 2020 22:30:17

US3642072

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:12:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 23:01:48

US3642072

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:12:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 23:01:48

US3642072

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
Data entry locked.	System	29 Sep 2020 23:01:48
User entered 'Day 3'	System	29 Sep 2020 23:01:48

US3642072

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:12:20

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 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-01T13:31:43', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '285b4c9b-ec4e-408e-83c8-acce527ad745'	System	01 Oct 2020 20:31:58
User entered 'None (1)'	System	01 Oct 2020 20:31:58

US3642072

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:12:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-01T13:31:46', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '285b4c9b-ec4e-408e-83c8-acce527ad745' User entered 'No (N)'	System	01 Oct 2020 20:31:58
	System	01 Oct 2020 20:31:58

US3642072

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-01T13:31:48', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '285b4c9b-ec4e-408e-83c8-acce527ad745' User entered 'No (N)'	System	01 Oct 2020 20:31:58
	System	01 Oct 2020 20:31:58

US3642072

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:12:20

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 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-01T13:31:51', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '285b4c9b-ec4e-408e-83c8-acce527ad745' User entered 'None (1)'	System	01 Oct 2020 20:31:58
	System	01 Oct 2020 20:31:58

US3642072

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:12:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-01T13:31:55', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '285b4c9b-ec4e-408e-83c8-acce527ad745' User entered '01 Oct 2020 13:31'	System	01 Oct 2020 20:31:58
	System	01 Oct 2020 20:31:58

US3642072

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:12:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 23:01:48

US3642072

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:12:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 23:01:48

US3642072

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
Data entry locked.	System	29 Sep 2020 23:01:48
User entered 'Day 4'	System	29 Sep 2020 23:01:48

US3642072

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:12:20

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 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-02T14:27:55', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '2b7cb0a6-a374-4f24-bc8d-df841497dbda' User entered 'None (1)'	System	02 Oct 2020 21:28:10
	System	02 Oct 2020 21:28:10

US3642072

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:12:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-02T14:27:59', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '2b7cb0a6-a374-4f24-bc8d-df841497dbda' User entered 'No (N)'	System	02 Oct 2020 21:28:10
	System	02 Oct 2020 21:28:10

US3642072

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-02T14:28:02', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '2b7cb0a6-a374-4f24-bc8d-df841497dbda' User entered 'No (N)'	System	02 Oct 2020 21:28:10
	System	02 Oct 2020 21:28:10

US3642072

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:12:20

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 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-02T14:28:05', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '2b7cb0a6-a374-4f24-bc8d-df841497dbda' User entered 'None (1)'	System	02 Oct 2020 21:28:10
	System	02 Oct 2020 21:28:10

US3642072

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:12:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-02T14:28:08', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '2b7cb0a6-a374-4f24-bc8d-df841497dbda' User entered '02 Oct 2020 14:28'	System	02 Oct 2020 21:28:10
	System	02 Oct 2020 21:28:10

US3642072

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:12:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 23:01:48

US3642072

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:12:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 23:01:48

US3642072

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
Data entry locked.	System	29 Sep 2020 23:01:48
User entered 'Day 5'	System	29 Sep 2020 23:01:48

US3642072

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:12:20

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 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-03T16:30:22', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'a4531caf-056c-4c2c-beca-cb2bd6112c64'	System	03 Oct 2020 23:30:38
User entered 'None (1)'	System	03 Oct 2020 23:30:38

US3642072

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:12:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-03T16:30:26', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'a4531caf-056c-4c2c-beca-cb2bd6112c64' User entered 'No (N)'	System	03 Oct 2020 23:30:38
	System	03 Oct 2020 23:30:38

US3642072

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-03T16:30:28', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'a4531caf-056c-4c2c-beca-cb2bd6112c64' User entered 'No (N)'	System	03 Oct 2020 23:30:38
	System	03 Oct 2020 23:30:38

US3642072

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:12:20

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 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-03T16:30:32', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'a4531caf-056c-4c2c-beca-cb2bd6112c64'	System	03 Oct 2020 23:30:38
User entered 'None (1)'	System	03 Oct 2020 23:30:38

US3642072

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:12:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-03T16:30:36', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'a4531caf-056c-4c2c-beca-cb2bd6112c64' User entered '03 Oct 2020 16:30'	System	03 Oct 2020 23:30:38
	System	03 Oct 2020 23:30:38

US3642072

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:12:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 23:01:48

US3642072

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:12:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 23:01:48

US3642072

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
Data entry locked.	System	29 Sep 2020 23:01:48
User entered 'Day 6'	System	29 Sep 2020 23:01:48

US3642072

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:12:20

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 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-04T15:00:08', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '324a5bcf-cbec-45ca-9d49-c0fa0a40fa15'	System	04 Oct 2020 22:00:24
User entered 'None (1)'	System	04 Oct 2020 22:00:24

US3642072

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:12:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-04T15:00:11', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '324a5bcf-cbec-45ca-9d49-c0fa0a40fa15' User entered 'No (N)'	System	04 Oct 2020 22:00:24
	System	04 Oct 2020 22:00:24

US3642072

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-04T15:00:13', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '324a5bcf-cbec-45ca-9d49-c0fa0a40fa15' User entered 'No (N)'	System	04 Oct 2020 22:00:24
	System	04 Oct 2020 22:00:24

US3642072

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:12:20

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 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-04T15:00:16', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '324a5bcf-cbec-45ca-9d49-c0fa0a40fa15' User entered 'None (1)'	System	04 Oct 2020 22:00:24
	System	04 Oct 2020 22:00:24

US3642072

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:12:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-04T15:00:19', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '324a5bcf-cbec-45ca-9d49-c0fa0a40fa15' User entered '04 Oct 2020 15:00'	System	04 Oct 2020 22:00:24
	System	04 Oct 2020 22:00:24

US3642072

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:12:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 23:01:48

US3642072

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:12:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 23:01:48

US3642072

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
Data entry locked.	System	29 Sep 2020 23:01:48
User entered 'Day 7'	System	29 Sep 2020 23:01:48

US3642072

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:12:20

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 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-05T14:55:40', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'c81499b2-6e3b-4a6e-ab47-02dc649ad9de' User entered 'None (1)'	System	05 Oct 2020 21:55:57
	System	05 Oct 2020 21:55:57

US3642072

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:12:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-05T14:55:44', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'c81499b2-6e3b-4a6e-ab47-02dc649ad9de' User entered 'No (N)'	System	05 Oct 2020 21:55:57
	System	05 Oct 2020 21:55:57

US3642072

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-05T14:55:47', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'c81499b2-6e3b-4a6e-ab47-02dc649ad9de' User entered 'No (N)'	System	05 Oct 2020 21:55:57
	System	05 Oct 2020 21:55:57

US3642072

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:12:20

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 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-05T14:55:51', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'c81499b2-6e3b-4a6e-ab47-02dc649ad9de' User entered 'None (1)'	System	05 Oct 2020 21:55:57
	System	05 Oct 2020 21:55:57

US3642072

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:12:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-05T14:55:54', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'c81499b2-6e3b-4a6e-ab47-02dc649ad9de' User entered '05 Oct 2020 14:55'	System	05 Oct 2020 21:55:57
	System	05 Oct 2020 21:55:57

US3642072

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:12:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 23:01:48

US3642072

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:12:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 23:01:48

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
Data entry locked.	System	29 Sep 2020 23:01:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 23:01:48

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:12:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-29T16:21:29', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '22114cf8-03d7-4fd2-ad01-480b462b57f2' User entered 'None (0)'	System	29 Sep 2020 23:21:51
	System	29 Sep 2020 23:21:51

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:12:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-29T16:21:32', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '22114cf8-03d7-4fd2-ad01-480b462b57f2' User entered 'None (0)'	System	29 Sep 2020 23:21:51
	System	29 Sep 2020 23:21:51

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:12:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-29T16:21:34', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '22114cf8-03d7-4fd2-ad01-480b462b57f2' User entered 'None (0)'	System	29 Sep 2020 23:21:51
	System	29 Sep 2020 23:21:51

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:12:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-29T16:21:37', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '22114cf8-03d7-4fd2-ad01-480b462b57f2' User entered 'None (0)'	System	29 Sep 2020 23:21:51
	System	29 Sep 2020 23:21:51

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:12:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-29T16:21:39', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '22114cf8-03d7-4fd2-ad01-480b462b57f2' User entered 'None (0)'	System	29 Sep 2020 23:21:51
	System	29 Sep 2020 23:21:51

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:12:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-29T16:21:42', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '22114cf8-03d7-4fd2-ad01-480b462b57f2' User entered 'None (0)'	System	29 Sep 2020 23:21:51
	System	29 Sep 2020 23:21:51

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:12:20

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 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-29T16:21:47', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '22114cf8-03d7-4fd2-ad01-480b462b57f2' User entered 'No (N)'	System	29 Sep 2020 23:21:51
	System	29 Sep 2020 23:21:51

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:12:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-29T16:21:49', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '22114cf8-03d7-4fd2-ad01-480b462b57f2' User entered '29 Sep 2020 16:21'	System	29 Sep 2020 23:21:51
	System	29 Sep 2020 23:21:51

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:12:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '29 Sep 2020 16:19'	System	29 Sep 2020 23:01:48

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:12:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '29 Sep 2020 18:49'	System	29 Sep 2020 23:01:48

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
Data entry locked.	System	29 Sep 2020 23:01:48
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 23:01:48

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:12:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-29T19:57:51', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'b0874c07-b357-4669-95ab-f6ffe915a83f' User entered 'None (0)'	System	30 Sep 2020 02:58:19
	System	30 Sep 2020 02:58:19

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:12:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-29T19:57:54', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'b0874c07-b357-4669-95ab-f6ffe915a83f' User entered 'None (0)'	System	30 Sep 2020 02:58:19
	System	30 Sep 2020 02:58:19

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:12:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-29T19:57:57', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'b0874c07-b357-4669-95ab-f6ffe915a83f' User entered 'None (0)'	System	30 Sep 2020 02:58:19
	System	30 Sep 2020 02:58:19

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:12:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-29T19:58:00', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'b0874c07-b357-4669-95ab-f6ffe915a83f' User entered 'None (0)'	System	30 Sep 2020 02:58:19
	System	30 Sep 2020 02:58:19

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:12:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-29T19:58:03', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'b0874c07-b357-4669-95ab-f6ffe915a83f' User entered 'None (0)'	System	30 Sep 2020 02:58:19
	System	30 Sep 2020 02:58:19

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:12:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-29T19:58:06', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'b0874c07-b357-4669-95ab-f6ffe915a83f' User entered 'None (0)'	System	30 Sep 2020 02:58:19
	System	30 Sep 2020 02:58:19

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:12:20

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 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-29T19:58:11', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'b0874c07-b357-4669-95ab-f6ffe915a83f' User entered 'No (N)'	System	30 Sep 2020 02:58:19
	System	30 Sep 2020 02:58:19

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:12:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-29T19:58:15', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'b0874c07-b357-4669-95ab-f6ffe915a83f' User entered '29 Sep 2020 19:58'	System	30 Sep 2020 02:58:19
	System	30 Sep 2020 02:58:19

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:12:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '29 Sep 2020 19:44'	System	29 Sep 2020 23:01:48

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:12:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 23:01:48

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
Data entry locked.	System	29 Sep 2020 23:01:48
User entered 'Day 2'	System	29 Sep 2020 23:01:48

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:12:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-30T15:30:23', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'e3b7e194-a0e6-43f4-8a7f-67155ff65576'	System	30 Sep 2020 22:31:10
User entered 'No interference with activity (1)'	System	30 Sep 2020 22:31:10

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:12:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-30T15:30:31', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'e3b7e194-a0e6-43f4-8a7f-67155ff65576'	System	30 Sep 2020 22:31:10
User entered 'Some interference with activity (2)'	System	30 Sep 2020 22:31:10

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:12:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-30T15:30:39', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'e3b7e194-a0e6-43f4-8a7f-67155ff65576'	System	30 Sep 2020 22:31:10
User entered 'No interference with activity (1)'	System	30 Sep 2020 22:31:10

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:12:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-30T15:30:45', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'e3b7e194-a0e6-43f4-8a7f-67155ff65576'	System	30 Sep 2020 22:31:10
User entered 'No interference with activity (1)'	System	30 Sep 2020 22:31:10

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:12:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-30T15:30:48', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'e3b7e194-a0e6-43f4-8a7f-67155ff65576' User entered 'None (0)'	System	30 Sep 2020 22:31:10
	System	30 Sep 2020 22:31:10

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:12:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-30T15:30:54', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'e3b7e194-a0e6-43f4-8a7f-67155ff65576'	System	30 Sep 2020 22:31:10
User entered 'No interference with activity (1)'	System	30 Sep 2020 22:31:10

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:12:20

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 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-30T15:30:57', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'e3b7e194-a0e6-43f4-8a7f-67155ff65576' User entered 'No (N)'	System	30 Sep 2020 22:31:10
	System	30 Sep 2020 22:31:10

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:12:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-09-30T15:31:08', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'e3b7e194-a0e6-43f4-8a7f-67155ff65576' User entered '30 Sep 2020 15:31'	System	30 Sep 2020 22:31:10
	System	30 Sep 2020 22:31:10

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:12:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 23:01:48

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:12:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 23:01:48

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
Data entry locked.	System	29 Sep 2020 23:01:48
User entered 'Day 3'	System	29 Sep 2020 23:01:48

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:12:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-01T13:32:18', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '67dd6543-1855-4394-9dba-f339ffdf2c6b'	System	01 Oct 2020 20:32:50
User entered 'No interference with activity (1)'	System	01 Oct 2020 20:32:50

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:12:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-01T13:32:24', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '67dd6543-1855-4394-9dba-f339ffdf2c6b'	System	01 Oct 2020 20:32:50
User entered 'No interference with activity (1)'	System	01 Oct 2020 20:32:50

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:12:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-01T13:32:29', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '67dd6543-1855-4394-9dba-f339ffdf2c6b'	System	01 Oct 2020 20:32:50
User entered 'No interference with activity (1)'	System	01 Oct 2020 20:32:50

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:12:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-01T13:32:32', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '67dd6543-1855-4394-9dba-f339ffdf2c6b'	System	01 Oct 2020 20:32:50
User entered 'No interference with activity (1)'	System	01 Oct 2020 20:32:50

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:12:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-01T13:32:35', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '67dd6543-1855-4394-9dba-f339ffdf2c6b' User entered 'None (0)'	System	01 Oct 2020 20:32:50
	System	01 Oct 2020 20:32:50

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:12:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-01T13:32:37', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '67dd6543-1855-4394-9dba-f339ffdf2c6b' User entered 'None (0)'	System	01 Oct 2020 20:32:50
	System	01 Oct 2020 20:32:50

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:12:20

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 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-01T13:32:41', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '67dd6543-1855-4394-9dba-f339ffdf2c6b' User entered 'No (N)'	System	01 Oct 2020 20:32:50
	System	01 Oct 2020 20:32:50

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:12:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-01T13:32:47', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '67dd6543-1855-4394-9dba-f339ffdf2c6b' User entered '01 Oct 2020 13:32'	System	01 Oct 2020 20:32:50
	System	01 Oct 2020 20:32:50

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:12:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 23:01:48

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:12:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 23:01:48

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
Data entry locked.	System	29 Sep 2020 23:01:48
User entered 'Day 4'	System	29 Sep 2020 23:01:48

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:12:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-02T14:28:13', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '1f1d5a40-6f1b-4b9e-abe5-a3516cb4e5d0' User entered 'None (0)'	System	02 Oct 2020 21:28:40
	System	02 Oct 2020 21:28:40

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:12:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-02T14:28:20', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '1f1d5a40-6f1b-4b9e-abe5-a3516cb4e5d0' User entered 'None (0)'	System	02 Oct 2020 21:28:40
	System	02 Oct 2020 21:28:40

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:12:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-02T14:28:23', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '1f1d5a40-6f1b-4b9e-abe5-a3516cb4e5d0' User entered 'None (0)'	System	02 Oct 2020 21:28:40
	System	02 Oct 2020 21:28:40

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:12:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-02T14:28:26', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '1f1d5a40-6f1b-4b9e-abe5-a3516cb4e5d0' User entered 'None (0)'	System	02 Oct 2020 21:28:40
	System	02 Oct 2020 21:28:40

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:12:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-02T14:28:29', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '1f1d5a40-6f1b-4b9e-abe5-a3516cb4e5d0' User entered 'None (0)'	System	02 Oct 2020 21:28:40
	System	02 Oct 2020 21:28:40

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:12:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-02T14:28:31', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '1f1d5a40-6f1b-4b9e-abe5-a3516cb4e5d0' User entered 'None (0)'	System	02 Oct 2020 21:28:40
	System	02 Oct 2020 21:28:40

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:12:20

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 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-02T14:28:34', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '1f1d5a40-6f1b-4b9e-abe5-a3516cb4e5d0' User entered 'No (N)'	System	02 Oct 2020 21:28:40
	System	02 Oct 2020 21:28:40

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:12:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-02T14:28:37', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '1f1d5a40-6f1b-4b9e-abe5-a3516cb4e5d0' User entered '02 Oct 2020 14:28'	System	02 Oct 2020 21:28:40
	System	02 Oct 2020 21:28:40

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:12:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 23:01:48

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:12:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 23:01:48

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
Data entry locked.	System	29 Sep 2020 23:01:48
User entered 'Day 5'	System	29 Sep 2020 23:01:48

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:12:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-03T16:30:41', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '0ab87037-c172-410b-a5cf-90f9857a1200' User entered 'None (0)'	System	03 Oct 2020 23:31:09
	System	03 Oct 2020 23:31:09

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:12:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-03T16:30:45', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '0ab87037-c172-410b-a5cf-90f9857a1200'	System	03 Oct 2020 23:31:09
User entered 'No interference with activity (1)'	System	03 Oct 2020 23:31:09

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:12:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-03T16:30:48', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '0ab87037-c172-410b-a5cf-90f9857a1200' User entered 'None (0)'	System	03 Oct 2020 23:31:09
	System	03 Oct 2020 23:31:09

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:12:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-03T16:30:51', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '0ab87037-c172-410b-a5cf-90f9857a1200' User entered 'None (0)'	System	03 Oct 2020 23:31:09
	System	03 Oct 2020 23:31:09

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:12:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-03T16:30:54', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '0ab87037-c172-410b-a5cf-90f9857a1200' User entered 'None (0)'	System	03 Oct 2020 23:31:09
	System	03 Oct 2020 23:31:09

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:12:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-03T16:30:59', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '0ab87037-c172-410b-a5cf-90f9857a1200' User entered 'None (0)'	System	03 Oct 2020 23:31:09
	System	03 Oct 2020 23:31:09

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:12:20

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 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-03T16:31:02', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '0ab87037-c172-410b-a5cf-90f9857a1200' User entered 'No (N)'	System	03 Oct 2020 23:31:09
	System	03 Oct 2020 23:31:09

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:12:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-03T16:31:08', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '0ab87037-c172-410b-a5cf-90f9857a1200' User entered '03 Oct 2020 16:31'	System	03 Oct 2020 23:31:09
	System	03 Oct 2020 23:31:09

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:12:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 23:01:48

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:12:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 23:01:48

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
Data entry locked.	System	29 Sep 2020 23:01:48
User entered 'Day 6'	System	29 Sep 2020 23:01:48

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:12:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-04T15:00:26', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '69520938-780d-4297-9f84-81cab6978a44' User entered 'None (0)'	System	04 Oct 2020 22:00:54
	System	04 Oct 2020 22:00:54

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:12:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-04T15:00:37', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '69520938-780d-4297-9f84-81cab6978a44'	System	04 Oct 2020 22:00:54
User entered 'No interference with activity (1)'	System	04 Oct 2020 22:00:54

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:12:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-04T15:00:40', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '69520938-780d-4297-9f84-81cab6978a44' User entered 'None (0)'	System	04 Oct 2020 22:00:54
	System	04 Oct 2020 22:00:54

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:12:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-04T15:00:42', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '69520938-780d-4297-9f84-81cab6978a44' User entered 'None (0)'	System	04 Oct 2020 22:00:54
	System	04 Oct 2020 22:00:54

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:12:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-04T15:00:44', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '69520938-780d-4297-9f84-81cab6978a44' User entered 'None (0)'	System	04 Oct 2020 22:00:54
	System	04 Oct 2020 22:00:54

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:12:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-04T15:00:46', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '69520938-780d-4297-9f84-81cab6978a44' User entered 'None (0)'	System	04 Oct 2020 22:00:54
	System	04 Oct 2020 22:00:54

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:12:20

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 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-04T15:00:49', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '69520938-780d-4297-9f84-81cab6978a44' User entered 'No (N)'	System	04 Oct 2020 22:00:54
	System	04 Oct 2020 22:00:54

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:12:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-04T15:00:52', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '69520938-780d-4297-9f84-81cab6978a44' User entered '04 Oct 2020 15:00'	System	04 Oct 2020 22:00:54
	System	04 Oct 2020 22:00:54

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:12:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 23:01:48

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:12:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 23:01:48

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
Data entry locked.	System	29 Sep 2020 23:01:48
User entered 'Day 7'	System	29 Sep 2020 23:01:48

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:12:20

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-05T14:55:59', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'efa29e3e-1a08-40f6-b62c-a6d82f33e30e' User entered 'None (0)'	System	05 Oct 2020 21:56:23
	System	05 Oct 2020 21:56:23

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:12:20

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-05T14:56:03', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'efa29e3e-1a08-40f6-b62c-a6d82f33e30e' User entered 'None (0)'	System	05 Oct 2020 21:56:23
	System	05 Oct 2020 21:56:23

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:12:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-05T14:56:05', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'efa29e3e-1a08-40f6-b62c-a6d82f33e30e' User entered 'None (0)'	System	05 Oct 2020 21:56:23
	System	05 Oct 2020 21:56:23

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:12:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-05T14:56:09', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'efa29e3e-1a08-40f6-b62c-a6d82f33e30e' User entered 'None (0)'	System	05 Oct 2020 21:56:23
	System	05 Oct 2020 21:56:23

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:12:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-05T14:56:11', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'efa29e3e-1a08-40f6-b62c-a6d82f33e30e' User entered 'None (0)'	System	05 Oct 2020 21:56:23
	System	05 Oct 2020 21:56:23

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:12:20

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-05T14:56:13', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'efa29e3e-1a08-40f6-b62c-a6d82f33e30e' User entered 'None (0)'	System	05 Oct 2020 21:56:23
	System	05 Oct 2020 21:56:23

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:12:20

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 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-05T14:56:19', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'efa29e3e-1a08-40f6-b62c-a6d82f33e30e' User entered 'No (N)'	System	05 Oct 2020 21:56:23
	System	05 Oct 2020 21:56:23

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:12:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-10-05T14:56:21', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'efa29e3e-1a08-40f6-b62c-a6d82f33e30e' User entered '05 Oct 2020 14:56'	System	05 Oct 2020 21:56:23
	System	05 Oct 2020 21:56:23

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:12:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 23:01:48

US3642072

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:12:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 23:01:48

US3642072

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:12:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Yes (Y)'	(b) (4) Colleen McLellan (b) (4)	07 Oct 2020 15:43:42

US3642072

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:12:20

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '7 Oct 2020'	Colleen McLellan (b) (4)	07 Oct 2020 15:43:42

US3642072

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:12:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Contact Made (CONTACT MADE)'	Colleen McLellan (b) (4)	07 Oct 2020 15:43:42

US3642072

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:12:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered empty.	Colleen McLellan (b) (4)	07 Oct 2020 15:43:42

US3642072

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Yes (Y)'	(b) (4) Colleen McLellan (b) (4)	07 Oct 2020 15:43:33

US3642072

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:12:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User entered 'I'	System	07 Oct 2020 15:43:33

US3642072

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:12:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Yes (Y)'	(b) (4) Nancy Tang (b) (4)	15 Oct 2020 18:57:02

US3642072

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:12:20

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '15 Oct 2020'	(b) (4) Nancy Tang (b) (4)	15 Oct 2020 18:57:02

US3642072

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:12:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Nancy Tang (b) (4)	15 Oct 2020 18:57:02

US3642072

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:12:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered empty.	(b) (4) Nancy Tang (b) (4)	15 Oct 2020 18:57:02

US3642072

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Yes (Y)'	(b) (4) Nancy Tang (b) (4)	15 Oct 2020 18:57:06

US3642072

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:12:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User entered 'I'	System	15 Oct 2020 18:57:06

US3642072

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:12:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Yes (Y)'	Jennifer Morales (b) (4)	22 Oct 2020 17:23:05

US3642072

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:12:20

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '22 Oct 2020'	Jennifer Morales (b) (4)	22 Oct 2020 17:23:05

US3642072

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:12:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Contact Made (CONTACT MADE)'	Jennifer Morales (b) (4)	22 Oct 2020 17:23:05

US3642072

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:12:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered empty.	Jennifer Morales (b) (4)	22 Oct 2020 17:23:05

US3642072

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Yes (Y)'	Jennifer Morales (b) (4)	22 Oct 2020 17:23:10

US3642072

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:12:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User entered 'I'	System	22 Oct 2020 17:23:10

US3642072

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:12:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Yes (Y)'	Son Do (b) (4)	30 Oct 2020 16:22:51

US3642072

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '27 Oct 2020'	Son Do (b) (4)	30 Oct 2020 16:22:51

US3642072

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Clinic (Clinic)'	Son Do (b) (4)	30 Oct 2020 16:22:51

US3642072

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:12:20

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User entered 'VISIT3'	System	30 Oct 2020 16:22:51

US3642072

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:12:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Yes (Y)'	Son Do (b) (4)	30 Oct 2020 16:23:18

US3642072

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:12:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '27 Oct 2020'	Son Do (b) (4)	30 Oct 2020 16:23:18

US3642072

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '15:20'	Son Do (b) (4)	30 Oct 2020 16:23:18

US3642072

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User entered '27 Oct 2020 15:20'	System	30 Oct 2020 16:23:18

US3642072

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '97.7' F	Son Do (b) (4)	30 Oct 2020 16:23:18

US3642072

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:12:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Oral (Oral)'	Son Do (b) (4)	30 Oct 2020 16:23:18

US3642072

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:12:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered empty.	Son Do (b) (4)	30 Oct 2020 16:23:18

US3642072

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:12:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '72'	Son Do (b) (4)	30 Oct 2020 16:23:18

US3642072

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:12:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User entered 'bpm'	System	30 Oct 2020 16:23:18

US3642072

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '18'	Son Do (b) (4)	30 Oct 2020 16:23:18

US3642072

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:12:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User entered 'breaths/min'	System	30 Oct 2020 16:23:18

US3642072

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '139'	Son Do (b) (4)	30 Oct 2020 16:23:18

US3642072

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:12:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User entered 'mmHg'	System	30 Oct 2020 16:23:18

US3642072

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '66'	Son Do (b) (4)	30 Oct 2020 16:23:18

US3642072

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:12:20

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User entered 'mmHg'	System	30 Oct 2020 16:23:18

US3642072

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:12:20

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58

US3642072

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:12:20

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58

US3642072

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:12:20

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Yes (Y)'	Son Do (b) (4)	30 Oct 2020 16:23:28

US3642072

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:12:20

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '27 Oct 2020'	Son Do (b) (4)	30 Oct 2020 16:23:28

US3642072

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:12:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Yes (Y)'	Son Do (b) (4)	30 Oct 2020 16:23:41

US3642072

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:12:20

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '27 Oct 2020'	Son Do (b) (4)	30 Oct 2020 16:23:41

US3642072

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '15:46'	Son Do (b) (4)	30 Oct 2020 16:23:41

US3642072

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User entered '27 Oct 2020 15:46'	System	30 Oct 2020 16:23:41

US3642072

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Yes (Y)'	Son Do (b) (4)	30 Oct 2020 16:23:47

US3642072

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:12:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User entered '1'	System	30 Oct 2020 16:23:47

US3642072

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
Data entry locked.	System	01 Sep 2020 23:18:57
User entered 'Day 64'	System	01 Sep 2020 23:18:57

US3642072

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[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 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-11-01T05:46:01', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '6a586b7e-8697-44e4-9e2c-9a388705e1c6' User entered 'No (N)'	System	01 Nov 2020 13:46:21
	System	01 Nov 2020 13:46:21

US3642072

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Have you been exposed to someone with 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 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-11-01T05:46:08', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '6a586b7e-8697-44e4-9e2c-9a388705e1c6'	System	01 Nov 2020 13:46:21
User entered 'No (N)'	System	01 Nov 2020 13:46:21

US3642072

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-11-01T05:46:16', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '6a586b7e-8697-44e4-9e2c-9a388705e1c6' User entered '01 Nov 2020 05:46:16'	System	01 Nov 2020 13:46:21
	System	01 Nov 2020 13:46:21

US3642072

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
Data entry locked.	System	01 Sep 2020 23:18:57
User entered '01 Nov 2020 00:01'	System	01 Sep 2020 23:18:57

US3642072

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
Data entry locked.	System	01 Sep 2020 23:18:57
User entered '05 Nov 2020 23:59'	System	01 Sep 2020 23:18:57

US3642072

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
Data entry locked.	System	01 Sep 2020 23:18:57
User entered 'Day 71'	System	01 Sep 2020 23:18:57

US3642072

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-11-09T17:35:21', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '429c896b-b037-4a91-8c72-cfaaf9d3ba94' User entered 'No (N)'	System	10 Nov 2020 01:35:38
	System	10 Nov 2020 01:35:38

US3642072

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

Have you been exposed to someone with 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 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-11-09T17:35:28', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '429c896b-b037-4a91-8c72-cfaaf9d3ba94' User entered 'No (N)'	System	10 Nov 2020 01:35:38
	System	10 Nov 2020 01:35:38

US3642072

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-11-09T17:35:36', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '429c896b-b037-4a91-8c72-cfaaf9d3ba94' User entered '09 Nov 2020 17:35:36'	System	10 Nov 2020 01:35:38
	System	10 Nov 2020 01:35:38

US3642072

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
Data entry locked.	System	01 Sep 2020 23:18:57
User entered '08 Nov 2020 00:01'	System	01 Sep 2020 23:18:57

US3642072

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
Data entry locked.	System	01 Sep 2020 23:18:57
User entered '12 Nov 2020 23:59'	System	01 Sep 2020 23:18:57

US3642072

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
Data entry locked.	System	01 Sep 2020 23:18:57
User entered 'Day 78'	System	01 Sep 2020 23:18:57

US3642072

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[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 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-11-17T12:00:35', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '187123e3-f269-4734-9d3b-db2baefa5c75'	System	17 Nov 2020 20:00:54
User entered 'No (N)'	System	17 Nov 2020 20:00:54

US3642072

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

Have you been exposed to someone with 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 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-11-17T12:00:44', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '187123e3-f269-4734-9d3b-db2baefa5c75'	System	17 Nov 2020 20:00:54
User entered 'No (N)'	System	17 Nov 2020 20:00:54

US3642072

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-11-17T12:00:51', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '187123e3-f269-4734-9d3b-db2baefa5c75' User entered '17 Nov 2020 12:00:51'	System	17 Nov 2020 20:00:54
	System	17 Nov 2020 20:00:54

US3642072

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
Data entry locked.	System	01 Sep 2020 23:18:57
User entered '15 Nov 2020 00:01'	System	01 Sep 2020 23:18:57

US3642072

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:06:08
Data entry locked.	System	01 Sep 2020 23:18:57
User entered '19 Nov 2020 23:59'	System	01 Sep 2020 23:18:57

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[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 (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-11-30T20:50:31', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '70241834-9935-4cb5-896a-8ce6b9e7156c' User entered 'Yes (Y)'	System	01 Dec 2020 04:51:27
	System	01 Dec 2020 04:51:27

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Have you been exposed to someone with 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 (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-11-30T20:50:40', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '70241834-9935-4cb5-896a-8ce6b9e7156c'	System	01 Dec 2020 04:51:27
User entered 'No (N)'	System	01 Dec 2020 04:51:27

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-11-30T20:50:45', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '70241834-9935-4cb5-896a-8ce6b9e7156c' User entered 'No (N)'	System	01 Dec 2020 04:51:27
	System	01 Dec 2020 04:51:27

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-11-30T20:50:55', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '70241834-9935-4cb5-896a-8ce6b9e7156c'	System	01 Dec 2020 04:51:27
User entered 'Yes (Y)'	System	01 Dec 2020 04:51:27

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-11-30T20:51:08', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '70241834-9935-4cb5-896a-8ce6b9e7156c'	System	01 Dec 2020 04:51:27
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	01 Dec 2020 04:51:27

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-11-30T20:51:17', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '70241834-9935-4cb5-896a-8ce6b9e7156c' User entered '30 Nov 2020 20:51:17'	System	01 Dec 2020 04:51:27
	System	01 Dec 2020 04:51:27

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[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 (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-12-03T00:10:25', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'fd7e241a-c701-4f2a-8070-5a690728d385' User entered 'No (N)'	System	03 Dec 2020 08:10:41
	System	03 Dec 2020 08:10:41

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

Have you been exposed to someone with 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 (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-12-03T00:10:30', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'fd7e241a-c701-4f2a-8070-5a690728d385'	System	03 Dec 2020 08:10:41
User entered 'No (N)'	System	03 Dec 2020 08:10:41

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-12-03T00:10:37', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'fd7e241a-c701-4f2a-8070-5a690728d385' User entered '03 Dec 2020 00:10:37'	System	03 Dec 2020 08:10:41
	System	03 Dec 2020 08:10:41

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[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 (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-12-10T16:16:34', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '54da4666-47d5-462c-9773-e73ff87a4c2c'	System	11 Dec 2020 00:17:21
User entered 'Yes (Y)'	System	11 Dec 2020 00:17:21

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

Have you been exposed to someone with 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 (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-12-10T16:16:38', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '54da4666-47d5-462c-9773-e73ff87a4c2c'	System	11 Dec 2020 00:17:21
User entered 'No (N)'	System	11 Dec 2020 00:17:21

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-12-10T16:16:42', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '54da4666-47d5-462c-9773-e73ff87a4c2c'	System	11 Dec 2020 00:17:21
User entered 'No (N)'	System	11 Dec 2020 00:17:21

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-12-10T16:17:02', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '54da4666-47d5-462c-9773-e73ff87a4c2c' User entered 'Yes (Y)'	System	11 Dec 2020 00:17:21
	System	11 Dec 2020 00:17:21

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-12-10T16:17:05', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '54da4666-47d5-462c-9773-e73ff87a4c2c'	System	11 Dec 2020 00:17:21
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	11 Dec 2020 00:17:21

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-12-10T16:17:13', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '54da4666-47d5-462c-9773-e73ff87a4c2c' User entered '10 Dec 2020 16:17:13'	System	11 Dec 2020 00:17:21
	System	11 Dec 2020 00:17:21

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[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 (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-12-19T12:00:24', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'c13fa842-cbcd-4c83-bd52-dd8885ec100c' User entered 'No (N)'	System	19 Dec 2020 20:00:42
	System	19 Dec 2020 20:00:42

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Have you been exposed to someone with 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 (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-12-19T12:00:31', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'c13fa842-cbcd-4c83-bd52-dd8885ec100c'	System	19 Dec 2020 20:00:42
User entered 'No (N)'	System	19 Dec 2020 20:00:42

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-12-19T12:00:38', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'c13fa842-cbcd-4c83-bd52-dd8885ec100c' User entered '19 Dec 2020 12:00:38'	System	19 Dec 2020 20:00:42
	System	19 Dec 2020 20:00:42

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[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 (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-12-24T11:25:59', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'f611a447-e332-4dd8-b630-2b5c7b160b92' User entered 'No (N)'	System	24 Dec 2020 19:26:13
	System	24 Dec 2020 19:26:13

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

Have you been exposed to someone with 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 (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-12-24T11:26:03', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'f611a447-e332-4dd8-b630-2b5c7b160b92' User entered 'No (N)'	System	24 Dec 2020 19:26:13
	System	24 Dec 2020 19:26:13

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-12-24T11:26:08', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'f611a447-e332-4dd8-b630-2b5c7b160b92'	System	24 Dec 2020 19:26:13
User entered '24 Dec 2020 11:26:08'	System	24 Dec 2020 19:26:13

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[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 (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-12-31T09:04:34', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '3d3a83b6-890b-4c58-9c6a-7a110c24ef63' User entered 'No (N)'	System	31 Dec 2020 17:04:48
	System	31 Dec 2020 17:04:48

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Have you been exposed to someone with 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 (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-12-31T09:04:38', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '3d3a83b6-890b-4c58-9c6a-7a110c24ef63' User entered 'No (N)'	System	31 Dec 2020 17:04:48
	System	31 Dec 2020 17:04:48

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2020-12-31T09:04:44', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '3d3a83b6-890b-4c58-9c6a-7a110c24ef63' User entered '31 Dec 2020 09:04:44'	System	31 Dec 2020 17:04:48
	System	31 Dec 2020 17:04:48

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[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 (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2021-01-07T14:21:04', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'dd23528e-c1f4-4df4-ba68-f12e342f020c' User entered 'No (N)'	System	07 Jan 2021 22:21:22
	System	07 Jan 2021 22:21:22

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Have you been exposed to someone with 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 (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2021-01-07T14:21:11', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'dd23528e-c1f4-4df4-ba68-f12e342f020c' User entered 'No (N)'	System	07 Jan 2021 22:21:22

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2021-01-07T14:21:18', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'dd23528e-c1f4-4df4-ba68-f12e342f020c' User entered '07 Jan 2021 14:21:18'	System	07 Jan 2021 22:21:22
	System	07 Jan 2021 22:21:22

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[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 (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2021-01-15T06:16:41', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'fe92ffbf-d521-4cf5-abf6-71dade359545'	System	15 Jan 2021 14:16:55
User entered 'No (N)'	System	15 Jan 2021 14:16:55

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

Have you been exposed to someone with 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 (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2021-01-15T06:16:48', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'fe92ffbf-d521-4cf5-abf6-71dade359545'	System	15 Jan 2021 14:16:55
User entered 'No (N)'	System	15 Jan 2021 14:16:55

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2021-01-15T06:16:53', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'fe92ffbf-d521-4cf5-abf6-71dade359545' User entered '15 Jan 2021 06:16:53'	System	15 Jan 2021 14:16:55
	System	15 Jan 2021 14:16:55

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[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 (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2021-01-23T12:00:53', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '6dc5bad3-636e-40ba-9d0c-187d5fe61028' User entered 'No (N)'	System	23 Jan 2021 20:01:17
	System	23 Jan 2021 20:01:17

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

Have you been exposed to someone with 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 (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2021-01-23T12:00:56', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '6dc5bad3-636e-40ba-9d0c-187d5fe61028'	System	23 Jan 2021 20:01:17
User entered 'No (N)'	System	23 Jan 2021 20:01:17

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2021-01-23T12:01:02', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '6dc5bad3-636e-40ba-9d0c-187d5fe61028' User entered '23 Jan 2021 12:01:02'	System	23 Jan 2021 20:01:17
	System	23 Jan 2021 20:01:17

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[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 (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2021-01-28T18:23:35', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'de5d8e44-0750-4bc1-a9cd-49a1a7966dd5' User entered 'No (N)'	System	29 Jan 2021 02:23:46

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

Have you been exposed to someone with 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 (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2021-01-28T18:23:38', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'de5d8e44-0750-4bc1-a9cd-49a1a7966dd5'	System	29 Jan 2021 02:23:46
User entered 'No (N)'	System	29 Jan 2021 02:23:46

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2021-01-28T18:23:43', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'de5d8e44-0750-4bc1-a9cd-49a1a7966dd5' User entered '28 Jan 2021 18:23:43'	System	29 Jan 2021 02:23:46

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[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 (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2021-02-04T16:13:55', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '672abffa-b53a-438d-b586-4c59f0795dc7' User entered 'No (N)'	System	05 Feb 2021 00:14:08
	System	05 Feb 2021 00:14:08

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

Have you been exposed to someone with 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 (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2021-02-04T16:13:58', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '672abffa-b53a-438d-b586-4c59f0795dc7'	System	05 Feb 2021 00:14:08
User entered 'No (N)'	System	05 Feb 2021 00:14:08

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2021-02-04T16:14:03', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '672abffa-b53a-438d-b586-4c59f0795dc7' User entered '04 Feb 2021 16:14:03'	System	05 Feb 2021 00:14:08
	System	05 Feb 2021 00:14:08

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[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 (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2021-02-11T10:00:57', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'e78841ce-fa2c-4cf1-830e-b9f2af6723a6' User entered 'No (N)'	System	11 Feb 2021 18:02:46
	System	11 Feb 2021 18:02:46

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

Have you been exposed to someone with 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 (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2021-02-11T10:01:00', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'e78841ce-fa2c-4cf1-830e-b9f2af6723a6'	System	11 Feb 2021 18:02:46
User entered 'No (N)'	System	11 Feb 2021 18:02:46

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2021-02-11T10:01:04', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'e78841ce-fa2c-4cf1-830e-b9f2af6723a6' User entered '11 Feb 2021 10:01:04'	System	11 Feb 2021 18:02:46
	System	11 Feb 2021 18:02:46

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[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 (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2021-02-18T08:01:09', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'fc7f131f-8533-4a80-b577-676f8b0bed31' User entered 'No (N)'	System	18 Feb 2021 16:01:21
	System	18 Feb 2021 16:01:21

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

Have you been exposed to someone with 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 (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2021-02-18T08:01:12', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'fc7f131f-8533-4a80-b577-676f8b0bed31'	System	18 Feb 2021 16:01:21
User entered 'No (N)'	System	18 Feb 2021 16:01:21

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2021-02-18T08:01:16', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'fc7f131f-8533-4a80-b577-676f8b0bed31' User entered '18 Feb 2021 08:01:16'	System	18 Feb 2021 16:01:21
	System	18 Feb 2021 16:01:21

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[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 (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2021-02-27T12:06:12-08:00', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '0480cb3f-8368-4154-9a50-884f5b86c02b' User entered 'No (N)'	System	27 Feb 2021 20:06:27
	System	27 Feb 2021 20:06:27

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

Have you been exposed to someone with 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 (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2021-02-27T12:06:17-08:00', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '0480cb3f-8368-4154-9a50-884f5b86c02b' User entered 'No (N)'	System	27 Feb 2021 20:06:27
	System	27 Feb 2021 20:06:27

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2021-02-27T12:06:21-08:00', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '0480cb3f-8368-4154-9a50-884f5b86c02b' User entered '27 Feb 2021 20:06:21'	System	27 Feb 2021 20:06:27
	System	27 Feb 2021 20:06:27

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[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 (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2021-03-04T10:56:40-08:00', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '7957e880-76b9-47c4-9971-b6e723e0a45f' User entered 'No (N)'	System	04 Mar 2021 18:56:51
	System	04 Mar 2021 18:56:51

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

Have you been exposed to someone with 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 (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2021-03-04T10:56:44-08:00', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '7957e880-76b9-47c4-9971-b6e723e0a45f' User entered 'No (N)'	System	04 Mar 2021 18:56:51
	System	04 Mar 2021 18:56:51

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2021-03-04T10:56:48-08:00', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '7957e880-76b9-47c4-9971-b6e723e0a45f' User entered '04 Mar 2021 10:56:48'	System	04 Mar 2021 18:56:51
	System	04 Mar 2021 18:56:51

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[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 (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2021-03-11T17:34:16-08:00', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'a9443c27-4cf4-4039-a3cb-4f75d5eacae6'	System	12 Mar 2021 01:34:29
User entered 'No (N)'	System	12 Mar 2021 01:34:29

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

Have you been exposed to someone with 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 (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2021-03-11T17:34:19-08:00', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'a9443c27-4cf4-4039-a3cb-4f75d5eacae6'	System	12 Mar 2021 01:34:29
User entered 'No (N)'	System	12 Mar 2021 01:34:29

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2021-03-11T17:34:22-08:00', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'a9443c27-4cf4-4039-a3cb-4f75d5eacae6'	System	12 Mar 2021 01:34:29
User entered '11 Mar 2021 17:34:22'	System	12 Mar 2021 01:34:29

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[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 (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2021-03-20T13:04:19-07:00', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '92e49fd7-3f48-4f62-8e83-432be4a9a2fe'	System	20 Mar 2021 20:04:32
User entered 'No (N)'	System	20 Mar 2021 20:04:32

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

Have you been exposed to someone with 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 (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2021-03-20T13:04:23-07:00', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '92e49fd7-3f48-4f62-8e83-432be4a9a2fe'	System	20 Mar 2021 20:04:32
User entered 'No (N)'	System	20 Mar 2021 20:04:32

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2021-03-20T13:04:27-07:00', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '92e49fd7-3f48-4f62-8e83-432be4a9a2fe' User entered '20 Mar 2021 13:04:27'	System	20 Mar 2021 20:04:32
	System	20 Mar 2021 20:04:32

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[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 (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2021-03-25T10:36:08-07:00', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'e6b364d2-68c3-433c-a410-6e06a7312584'	System	25 Mar 2021 17:36:19
User entered 'No (N)'	System	25 Mar 2021 17:36:19

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Have you been exposed to someone with 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 (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2021-03-25T10:36:11-07:00', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'e6b364d2-68c3-433c-a410-6e06a7312584'	System	25 Mar 2021 17:36:19
User entered 'No (N)'	System	25 Mar 2021 17:36:19

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2021-03-25T10:36:15-07:00', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: 'e6b364d2-68c3-433c-a410-6e06a7312584'	System	25 Mar 2021 17:36:19
User entered '25 Mar 2021 10:36:15'	System	25 Mar 2021 17:36:19

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[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 (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2021-04-02T08:39:36-07:00', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '33a230e0-e997-4e18-82ce-288cc9fd747e' User entered 'No (N)'	System	02 Apr 2021 15:39:48
	System	02 Apr 2021 15:39:48

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

Have you been exposed to someone with 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 (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2021-04-02T08:39:39-07:00', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '33a230e0-e997-4e18-82ce-288cc9fd747e' User entered 'No (N)'	System	02 Apr 2021 15:39:48

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2021-04-02T08:39:43-07:00', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '33a230e0-e997-4e18-82ce-288cc9fd747e' User entered '02 Apr 2021 08:39:43'	System	02 Apr 2021 15:39:48
	System	02 Apr 2021 15:39:48

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[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 (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2021-04-10T16:46:51-07:00', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '10523d4f-abc1-4628-aaf3-dc87ed9db52c'	System	10 Apr 2021 23:47:01
User entered 'No (N)'	System	10 Apr 2021 23:47:01

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Have you been exposed to someone with 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 (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2021-04-10T16:46:55-07:00', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '10523d4f-abc1-4628-aaf3-dc87ed9db52c'	System	10 Apr 2021 23:47:01
User entered 'No (N)'	System	10 Apr 2021 23:47:01

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2021-04-10T16:46:59-07:00', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '10523d4f-abc1-4628-aaf3-dc87ed9db52c'	System	10 Apr 2021 23:47:01
User entered '10 Apr 2021 16:46:59'	System	10 Apr 2021 23:47:01

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[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 (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2021-04-16T07:02:33-07:00', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '22e25702-1d66-42c8-836d-9cdf6f8f30f7'	System	16 Apr 2021 14:02:43
User entered 'No (N)'	System	16 Apr 2021 14:02:43

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Have you been exposed to someone with 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 (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2021-04-16T07:02:36-07:00', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '22e25702-1d66-42c8-836d-9cdf6f8f30f7'	System	16 Apr 2021 14:02:43
User entered 'No (N)'	System	16 Apr 2021 14:02:43

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2021-04-16T07:02:40-07:00', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '22e25702-1d66-42c8-836d-9cdf6f8f30f7'	System	16 Apr 2021 14:02:43
User entered '16 Apr 2021 07:02:40'	System	16 Apr 2021 14:02:43

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[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 (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2021-04-23T11:48:12-07:00', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '849eda02-2e3d-448d-ba66-9d85fbd90ce0' User entered 'No (N)'	System	23 Apr 2021 18:48:23
	System	23 Apr 2021 18:48:23

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Have you been exposed to someone with 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 (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2021-04-23T11:48:15-07:00', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '849eda02-2e3d-448d-ba66-9d85fbd90ce0' User entered 'No (N)'	System	23 Apr 2021 18:48:23

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2021-04-23T11:48:19-07:00', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '849eda02-2e3d-448d-ba66-9d85fbd90ce0'	System	23 Apr 2021 18:48:23
User entered '23 Apr 2021 11:48:19'	System	23 Apr 2021 18:48:23

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[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 (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2021-04-29T07:56:00-07:00', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '28a9f911-a6b2-4514-a779-108775a30a81'	System	29 Apr 2021 15:15:38
User entered 'No (N)'	System	29 Apr 2021 15:15:38

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

Have you been exposed to someone with 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 (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2021-04-29T07:56:03-07:00', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '28a9f911-a6b2-4514-a779-108775a30a81'	System	29 Apr 2021 15:15:38
User entered 'No (N)'	System	29 Apr 2021 15:15:38

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2021-04-29T07:56:07-07:00', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '28a9f911-a6b2-4514-a779-108775a30a81'	System	29 Apr 2021 15:15:38
User entered '29 Apr 2021 07:56:07'	System	29 Apr 2021 15:15:38

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '13 Oct 2022 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '17 Oct 2022 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '20 Oct 2022 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '24 Oct 2022 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '27 Oct 2022 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '31 Oct 2022 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '03 Nov 2022 00:01'	System	19 Nov 2020 22:06:36

US3642072

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:12:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:06:36
Amendment Manager: User entered '07 Nov 2022 23:59'	System	19 Nov 2020 22:06:36

US3642072

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:12:20

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)	30 Apr 2021 19:02:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2021-02-27T12:06:31-08:00', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '50781d55-9eca-4f37-97ce-e333418624e2'	System	27 Feb 2021 20:06:39
User entered 'No (N)'	System	27 Feb 2021 20:06:39

US3642072

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:12:20

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:02:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (32794B92-EAEA-43D9-A302-85C479168093)', Time: '2021-02-27T12:06:35-08:00', User OID: 'PatientReportedOutcome (US3642072)', ODM File OID: '50781d55-9eca-4f37-97ce-e333418624e2' User entered '27 Feb 2021 20:06:35'	System	27 Feb 2021 20:06:39
	System	27 Feb 2021 20:06:39

US3642072

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:12:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Yes (Y)'	(b) (4) Nancy Tang (b) (4)	06 Jan 2021 21:50:23

US3642072

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:12:20

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '25 Nov 2020'	(b) (4) Nancy Tang (b) (4)	06 Jan 2021 21:50:23

US3642072

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:12:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Nancy Tang (b) (4)	06 Jan 2021 21:50:23

US3642072

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:12:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered empty.	(b) (4) Nancy Tang (b) (4)	06 Jan 2021 21:50:23

US3642072

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Yes (Y)'	(b) (4) Nancy Tang (b) (4)	06 Jan 2021 21:50:27

US3642072

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:12:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 09:16:58
User entered 'I'	System	06 Jan 2021 21:50:27

US3642072

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:12:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:39
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Yes (Y)'	(b) (4) Nancy Tang (b) (4)	06 Jan 2021 21:55:34

US3642072

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:12:20

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:39
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '14 Dec 2020'	(b) (4) Nancy Tang (b) (4)	06 Jan 2021 21:55:34

US3642072

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:12:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:39
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Nancy Tang (b) (4)	06 Jan 2021 21:55:34

US3642072

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:12:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:39
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered empty.	(b) (4) Nancy Tang (b) (4)	06 Jan 2021 21:55:34

US3642072

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:39
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Yes (Y)'	(b) (4) Nancy Tang (b) (4)	06 Jan 2021 21:55:40

US3642072

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:12:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:39
User entered 'I'	System	06 Jan 2021 21:55:40

US3642072

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:12:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:39
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Yes (Y)'	(b) (4) Lindsey Woronicz (b) (4)	27 Jan 2021 20:05:40

US3642072

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:12:20

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:39
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '25 Jan 2021'	(b) (4) Lindsey Woronicz (b) (4)	27 Jan 2021 20:05:40

US3642072

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:12:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:39
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Lindsey Woronicz (b) (4)	27 Jan 2021 20:05:40

US3642072

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:12:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:39
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered empty.	(b) (4) Lindsey Woronicz (b) (4)	27 Jan 2021 20:05:40

US3642072

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:39
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Yes (Y)'	(b) (4) Lindsey Woronicz (b) (4)	27 Jan 2021 20:05:47

US3642072

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:12:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:39
User entered 'I'	System	27 Jan 2021 20:05:47

US3642072

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:12:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:39
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
User entered 'Yes (Y)'	Jennifer Morales (b) (4)	02 Mar 2021 00:55:58

US3642072

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:12:20

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:39
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
User entered '01 Mar 2021'	Jennifer Morales (b) (4)	02 Mar 2021 00:55:58

US3642072

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:12:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:39
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
User entered 'Contact Made (CONTACT MADE)'	Jennifer Morales (b) (4)	02 Mar 2021 00:55:58

US3642072

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:12:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:39
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
User entered empty.	Jennifer Morales (b) (4)	02 Mar 2021 00:55:58

US3642072

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:39
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
User entered 'Yes (Y)'	Jennifer Morales (b) (4)	02 Mar 2021 00:56:03

US3642072

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:12:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:39
User entered 'I'	System	02 Mar 2021 00:56:03

US3642072

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:12:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:39
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:16:54
User entered 'Yes (Y)'	Son Do (b) (4)	24 Mar 2021 15:08:12

US3642072

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:39
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:16:54
User entered '18 Mar 2021'	Son Do (b) (4)	24 Mar 2021 15:08:12

US3642072

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:39
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:16:54
User entered 'Clinic (Clinic)'	Son Do (b) (4)	24 Mar 2021 15:08:12

US3642072

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:12:20

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:39
User entered 'VISIT4'	System	24 Mar 2021 15:08:12

US3642072

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:12:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:39
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered 'No (N)'	(b) (4) Benjamin Hull (b) (4)	30 Mar 2021 19:53:45

US3642072

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:12:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:39
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered empty.	(b) (4) Benjamin Hull (b) (4)	30 Mar 2021 19:53:45

US3642072

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:39
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered empty.	(b) (4) Benjamin Hull (b) (4) (b) (4)	30 Mar 2021 19:53:45

US3642072

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:39
User entered empty.	System	30 Mar 2021 19:53:45

US3642072

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:12:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:39
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered empty.	(b) (4) Benjamin Hull (b) (4)	30 Mar 2021 19:53:45

US3642072

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:12:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:39
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered empty.	(b) (4) Benjamin Hull (b) (4) (b) (4)	30 Mar 2021 19:53:45

US3642072

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:12:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:39
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered empty.	(b) (4) Benjamin Hull (b) (4) (b) (4)	30 Mar 2021 19:53:45

US3642072

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:12:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:39
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered empty.	Benjamin Hull (b) (4)	30 Mar 2021 19:53:45

US3642072

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:12:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:39
User entered empty.	System	30 Mar 2021 19:53:45

US3642072

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:39
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered empty.	(b) (4) Benjamin Hull (b) (4)	30 Mar 2021 19:53:45

US3642072

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:12:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:39
User entered empty.	System	30 Mar 2021 19:53:45

US3642072

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:12:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:39
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered empty.	(b) (4) Benjamin Hull (b) (4)	30 Mar 2021 19:53:45

US3642072

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:12:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:39
User entered empty.	System	30 Mar 2021 19:53:45

US3642072

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:12:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:39
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered empty.	Benjamin Hull (b) (4)	30 Mar 2021 19:53:45

US3642072

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:12:20

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:39
User entered empty.	System	30 Mar 2021 19:53:45

US3642072

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:12:20

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:39

US3642072

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:12:20

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:39

US3642072

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:12:20

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:39
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:16:54
User entered 'No (N)'	Son Do (b) (4)	24 Mar 2021 15:08:18

US3642072

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:12:20

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:39
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:16:54
User entered empty.	Son Do (b) (4)	24 Mar 2021 15:08:18

US3642072

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:12:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:39
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:16:54
User entered 'Yes (Y)'	Son Do (b) (4)	24 Mar 2021 15:08:35

US3642072

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:12:20

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:39
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:16:54
User entered '18 Mar 2021'	Son Do (b) (4)	24 Mar 2021 15:08:35

US3642072

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:39
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:16:54
User entered '14:15'	Son Do (b) (4)	24 Mar 2021 15:08:35

US3642072

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:39
User entered '18 Mar 2021 14:15'	System	24 Mar 2021 15:08:35

US3642072

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:39
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:16:54
User entered 'Yes (Y)'	Son Do (b) (4)	24 Mar 2021 15:08:41

US3642072

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:12:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 10:29:39
User entered 'I'	System	24 Mar 2021 15:08:41

US3642072

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:12:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	28 Apr 2021 21:21:10
	(b) (4)	
User entered 'Yes (Y)'	Colleen McLellan (b) (4)	27 Apr 2021 17:47:29
	(b) (4)	

US3642072

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:12:20

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	28 Apr 2021 21:21:10
	(b) (4)	
User entered '27 Apr 2021'	Colleen McLellan (b) (4)	27 Apr 2021 17:47:29
	(b) (4)	

US3642072

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:12:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	28 Apr 2021 21:21:10
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Colleen McLellan (b) (4)	27 Apr 2021 17:47:29
	(b) (4)	

US3642072

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:12:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	28 Apr 2021 21:21:10
	(b) (4)	
User entered empty.	Colleen McLellan (b) (4)	27 Apr 2021 17:47:29
	(b) (4)	

US3642072

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	28 Apr 2021 21:21:10
	(b) (4)	
User entered 'Yes (Y)'	Colleen McLellan (b) (4)	27 Apr 2021 17:47:36
	(b) (4)	

US3642072

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:12:20

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	27 Apr 2021 17:47:36

US3642072

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

Form: Visit Date

Generated On: 10 Jun 2021 09:12:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Yes (Y)'	Son Do (b) (4)	20 Jan 2021 16:01:06

US3642072

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

Form: Visit Date

Generated On: 10 Jun 2021 09:12:20

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 26JAN2021 is recorded under Participant Decision Visit OL-D1/OL-1 visit in EDC, however the same is missing in PPD Central Lab. Please confirm if the sample dated 26JAN2021 is shipped and review Preclarus and kindly update tin query response to confirm with GCL records. Thank you.' (Site from DM).		26 Apr 2021 09:10:24
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 26JAN2021 is recorded under Participant Decision Visit OL-D1/OL-1 visit in EDC, however the same is missing in PPD Central Lab. Please confirm if the sample dated 26JAN2021 is shipped and review Preclarus and kindly update tin query response to confirm with GCL records. Thank you.' answered with 'the 26th jan 2021 date was entered in error; this participant did not have a visit on 26 Jan; only on 16 january. The additional sample is likely incorrectly assigned to this participant. All specimens for this visit were collected on 16jan2021. The lab staff will look into the erroneously collected sample. ' (Site from DM).	Megan Loughran (b) (4) (b) (4)	22 Apr 2021 18:34:06
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 26JAN2021 is recorded under Participant Decision Visit OL-D1/OL-1 visit in EDC, however the same is missing in PPD Central Lab. Please confirm if the sample dated 26JAN2021 is shipped and review Preclarus and kindly update tin query response to confirm with GCL records. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 10:54:37
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:37:12
User entered '16 Jan 2021'	Son Do (b) (4)	20 Jan 2021 16:01:06

US3642072

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

Form: Visit Date

Generated On: 10 Jun 2021 09:12:20

[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 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Clinic (Clinic)'	Son Do (b) (4)	20 Jan 2021 16:01:06

US3642072

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

Form: Visit Date

Generated On: 10 Jun 2021 09:12:20

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User entered 'UNBLND_DECIDE'	System	20 Jan 2021 16:01:06

US3642072

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

Form: Unblinding

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '16 Jan 2021'	Son Do (b) (4)	20 Jan 2021 16:01:35

US3642072

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

Form: Unblinding

Generated On: 10 Jun 2021 09:12:20

[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 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Mar 2021 02:12:44
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:18:25

US3642072

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

Form: Unblinding

Generated On: 10 Jun 2021 09:12:20

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Yes (Y)'	Son Do (b) (4)	20 Jan 2021 16:01:35

US3642072

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

Form: Unblinding

Generated On: 10 Jun 2021 09:12:20

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	19 Apr 2021 18:01:49
User closed query ' Per CDM, per Sponsor Review:Per IRT/EDC reports subject was unblinded under Amendment 5, but 'Under what version of the Protocol was the Participant unblinded?' is either blank or states 'Unblinded under A6 or later'. Please update data as appropriate on this field of Unblinding form. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:15:10
Query ' Per CDM, per Sponsor Review:Per IRT/EDC reports subject was unblinded under Amendment 5, but 'Under what version of the Protocol was the Participant unblinded?' is either blank or states 'Unblinded under A6 or later'. Please update data as appropriate on this field of Unblinding form. ' answered with 'corrected' (Site from DM).	Benjamin Hull (b) (4) (b) (4)	09 Apr 2021 18:39:27
Signature has been broken.	Benjamin Hull (b) (4) (b) (4)	09 Apr 2021 18:39:20
User entered 'Amendment 5 (Amendment 5)' reason for change: Data Entry Error	Benjamin Hull (b) (4) (b) (4)	09 Apr 2021 18:39:20
User opened query ' Per CDM, per Sponsor Review:Per IRT/EDC reports subject was unblinded under Amendment 5, but 'Under what version of the Protocol was the Participant unblinded?' is either blank or states 'Unblinded under A6 or later'. Please update data as appropriate on this field of Unblinding form. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 01:23:32
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Mar 2021 02:12:44
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:18:25

US3642072

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

Form: Unblinding

Generated On: 10 Jun 2021 09:12:20

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User closed query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	28 Jan 2021 10:53:52
Query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' answered with 'Data are correct. Subject unblinding occurred prior to date of consent form. PD reported.' (Site from System).	Colleen McLellan (b) (4) (b) (4)	26 Jan 2021 22:54:22
User opened query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	System	20 Jan 2021 16:01:35
User entered '28 Dec 2020'	Son Do (b) (4)	20 Jan 2021 16:01:35

US3642072

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

Form: Unblinding

Generated On: 10 Jun 2021 09:12:20

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Placebo (Placebo)'	Son Do (b) (4)	20 Jan 2021 16:01:35

US3642072

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

Form: Unblinding

Generated On: 10 Jun 2021 09:12:20

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Placebo (Placebo)'	Son Do (b) (4)	20 Jan 2021 16:01:35

US3642072

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

Form: Unblinding

Generated On: 10 Jun 2021 09:12:20

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Placebo (Placebo)'	Son Do (b) (4)	20 Jan 2021 16:01:35

US3642072

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

Form: Unblinding

Generated On: 10 Jun 2021 09:12:20

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Yes (Y)'	Son Do (b) (4)	20 Jan 2021 16:01:35

US3642072

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

Form: Unblinding

Generated On: 10 Jun 2021 09:12:20

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User entered '1'	System	20 Jan 2021 16:01:35

US3642072

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

Form: Unblinding

Generated On: 10 Jun 2021 09:12:20

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User entered 'I'	System	20 Jan 2021 16:01:35

US3642072

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:12:20

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered missing code ND - Not Done.	Son Do (b) (4)	20 Jan 2021 16:03:32

US3642072

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:12:20

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered missing code ND - Not Done.	Son Do (b) (4)	20 Jan 2021 16:03:32

US3642072

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:12:20

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User entered empty.	System	20 Jan 2021 16:03:32
DataPoint set to visible.	System	20 Jan 2021 16:01:35

US3642072

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:12:20

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered missing code ND - Not Done.	Son Do (b) (4)	20 Jan 2021 16:03:32

US3642072

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:12:20

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered missing code ND - Not Done.	Son Do (b) (4)	20 Jan 2021 16:03:32

US3642072

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:12:20

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User entered empty.	System	20 Jan 2021 16:03:32
DataPoint set to visible.	System	20 Jan 2021 16:01:35

US3642072

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:12:20

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User accepted default value 'Pre-Dose (PREDOSE)'	Son Do (b) (4)	20 Jan 2021 16:03:32

US3642072

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:12:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Yes (Y)'	Son Do (b) (4)	20 Jan 2021 16:03:32

US3642072

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:12:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '16 Jan 2021'	Son Do (b) (4)	20 Jan 2021 16:03:32

US3642072

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '13:22'	Son Do (b) (4)	20 Jan 2021 16:03:32

US3642072

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User entered '16 Jan 2021 13:22'	System	20 Jan 2021 16:03:32

US3642072

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:12:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '98.1' F	Son Do (b) (4)	20 Jan 2021 16:03:32

US3642072

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:12:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Oral (Oral)'	Son Do (b) (4)	20 Jan 2021 16:03:32

US3642072

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:12:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered empty.	Son Do (b) (4)	20 Jan 2021 16:03:32

US3642072

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:12:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '75'	Son Do (b) (4)	20 Jan 2021 16:03:32

US3642072

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:12:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User entered 'bpm'	System	20 Jan 2021 16:03:32

US3642072

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '16'	Son Do (b) (4)	20 Jan 2021 16:03:32

US3642072

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:12:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User entered 'breaths/min'	System	20 Jan 2021 16:03:32

US3642072

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '124'	Son Do (b) (4)	20 Jan 2021 16:03:32

US3642072

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:12:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User entered 'mmHg'	System	20 Jan 2021 16:03:32

US3642072

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '73'	Son Do (b) (4)	20 Jan 2021 16:03:32

US3642072

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:12:20

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User entered 'mmHg'	System	20 Jan 2021 16:03:32

US3642072

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:12:20

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered missing code ND - Not Done.	Son Do (b) (4)	20 Jan 2021 16:03:32

US3642072

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:12:20

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered missing code ND - Not Done.	Son Do (b) (4)	20 Jan 2021 16:03:32

US3642072

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:12:20

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User entered empty.	System	20 Jan 2021 16:03:32
DataPoint set to visible.	System	20 Jan 2021 16:01:35

US3642072

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:12:20

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User accepted default value 'Post-Dose (POSTDOSE)'	Son Do (b) (4)	20 Jan 2021 16:03:32

US3642072

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:12:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Yes (Y)'	Son Do (b) (4)	20 Jan 2021 16:03:32

US3642072

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:12:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '16 Jan 2021'	Son Do (b) (4)	20 Jan 2021 16:03:32

US3642072

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:16:54
Signature has been broken.	Son Do (b) (4)	24 Mar 2021 15:11:25
User entered '16:05' reason for change: Data Entry Error	Son Do (b) (4)	24 Mar 2021 15:11:25
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '14:05'	Son Do (b) (4)	20 Jan 2021 16:03:32

US3642072

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User entered '16 Jan 2021 16:05'	System	24 Mar 2021 15:11:25
User entered '16 Jan 2021 14:05'	System	20 Jan 2021 16:03:32

US3642072

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '97.9' F	Son Do (b) (4)	20 Jan 2021 16:03:32

US3642072

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:12:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Oral (Oral)'	Son Do (b) (4)	20 Jan 2021 16:03:32

US3642072

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:12:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered empty.	Son Do (b) (4)	20 Jan 2021 16:03:32

US3642072

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:12:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '65'	Son Do (b) (4)	20 Jan 2021 16:03:32

US3642072

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:12:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User entered 'bpm'	System	20 Jan 2021 16:03:32

US3642072

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '17'	Son Do (b) (4)	20 Jan 2021 16:03:32

US3642072

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:12:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User entered 'breaths/min'	System	20 Jan 2021 16:03:32

US3642072

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '126'	Son Do (b) (4)	20 Jan 2021 16:03:32

US3642072

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:12:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User entered 'mmHg'	System	20 Jan 2021 16:03:32

US3642072

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '77'	Son Do (b) (4)	20 Jan 2021 16:03:32

US3642072

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:12:20

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User entered 'mmHg'	System	20 Jan 2021 16:03:32

US3642072

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

Form: Physical Examination

Generated On: 10 Jun 2021 09:12:20

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'No (N)'	Son Do (b) (4)	20 Jan 2021 16:03:58

US3642072

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

Form: Physical Examination

Generated On: 10 Jun 2021 09:12:20

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered empty.	Son Do (b) (4)	20 Jan 2021 16:03:58

US3642072

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

Form: Exposure

Generated On: 10 Jun 2021 09:12:20

[Was study treatment given?](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: Was study treatment given is yes but there is no corresponding information in IRT. If data needs to be added to IRT, please submit a data correction request ASAP and confirm once done.' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 18:33:48
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Yes (Y)'	Son Do (b) (4)	20 Jan 2021 16:04:18

US3642072

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

Form: Exposure

Generated On: 10 Jun 2021 09:12:20

[If No, reason not given](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered empty.	(b) (4) Son Do (b) (4)	20 Jan 2021 16:04:18

US3642072

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

Form: Exposure

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered empty.	(b) (4) Son Do (b) (4)	20 Jan 2021 16:04:18

US3642072

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

Form: Exposure

Generated On: 10 Jun 2021 09:12:20

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
User entered 'mRNA-1273'	System	20 Jan 2021 16:04:18
DataPoint set to visible.	System	20 Jan 2021 16:01:35

US3642072

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

Form: Exposure

Generated On: 10 Jun 2021 09:12:20

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per CDA, per sponsor review: Per IRT, Subject did not enter open label treatment or data was not entered in IRT . Please review and reconcile. ' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 07:21:52
Query 'Per CDA, per sponsor review: Per IRT, Subject did not enter open label treatment or data was not entered in IRT . Please review and reconcile. ' answered with 'edc is correct. Pt was inadvertently unblinded early, however, she did still qualify for open label dosing. an epip was filed and permission was granted to enter subject. A data change form was submitted to add PID back into IRT but upon patient visit, the PID did not show up in the list in IRT. the pharmacy was able to manually dispense study drug per pharmacy protocol. CRM was notified of situation. ' (Site from DM).	Megan Loughran (b) (4) (b) (4)	09 Apr 2021 22:41:46
Query 'Per CDA, per sponsor review: Per IRT, Subject had Open Label Day1 Treatment on 21JAN2021. Please review and reconcile. ' canceled (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 00:32:07
User opened query 'Per CDA, per sponsor review: Per IRT, Subject did not enter open label treatment or data was not entered in IRT . Please review and reconcile. ' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 00:32:02
User opened query 'Per CDA, per sponsor review: Per IRT, Subject had Open Label Day1 Treatment on 21JAN2021. Please review and reconcile. ' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 00:31:09
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:37:12
User entered '16 Jan 2021'	Son Do (b) (4)	20 Jan 2021 16:04:18

US3642072

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

Form: Exposure

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '15:34'	(b) (4) Son Do (b) (4)	20 Jan 2021 16:04:18

US3642072

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

Form: Exposure

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
User entered '16 Jan 2021 15:34'	System	20 Jan 2021 16:04:18

US3642072

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

Form: Exposure

Generated On: 10 Jun 2021 09:12:20

Which arm was used to give treatment?

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Left Arm (LEFT ARM)'	(b) (4) Son Do (b) (4)	20 Jan 2021 16:04:18

US3642072

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

Form: Exposure

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	20 Jan 2021 16:04:18

US3642072

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

Form: Exposure

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	20 Jan 2021 16:04:18

US3642072

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:12:20

Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User closed query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: RQ1: As per response "Corrected in PPD". However, per preclarus, the sample dated 26JAN2021 is still under UNSCHEDULED visit in PPD Central labs. Please reconcile and review preclarus and update as appropriate, else clarify.' (Site from DM).		19 Apr 2021 10:16:44
Query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: RQ1: As per response "Corrected in PPD". However, per preclarus, the sample dated 26JAN2021 is still under UNSCHEDULED visit in PPD Central labs. Please reconcile and review preclarus and update as appropriate, else clarify.'	Megan Loughran (b) (4)	14 Apr 2021 15:53:58
answered with 'data in edc are correct. PPD has been called a second time for the requested change, and have confirmed that it has been corrected.' (Site from DM).	(b) (4)	
User opened query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: RQ1: As per response "Corrected in PPD". However, per preclarus, the sample dated 26JAN2021 is still under UNSCHEDULED visit in PPD Central labs. Please reconcile and review preclarus and update as appropriate, else clarify.' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 06:46:16
User closed query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Sample dated 26JAN2021 is recorded under Participant Decision Visit / OL-D1 in EDC, however the same is reported under Unscheduled visit in PPD Central lab. Please reconcile the correct Visit and confirm in query response. Else clarify, Thank you ' (Site from DM).		12 Apr 2021 06:46:16
Query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Sample dated 26JAN2021 is recorded under Participant Decision Visit / OL-D1 in EDC, however the same is reported under Unscheduled visit in PPD Central lab. Please reconcile the correct Visit and confirm in query response. Else clarify, Thank you ' answered with 'Corrected in PPD' (Site from DM).	Benjamin Hull (b) (4)	09 Apr 2021 18:54:59
	(b) (4)	

US3642072

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:12:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Sample dated 26JAN2021 is recorded under Participant Decision Visit / OL-D1 in EDC, however the same is reported under Unscheduled visit in PPD Central lab. Please reconcile the correct Visit and confirm in query response. Else clarify, Thank you ' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	21 Mar 2021 13:13:09
	(b) (4)	
	Stephen Spector	(b) (4) 06 Mar 2021 01:40:21
	(b) (4)	
User entered 'Yes (Y)'	Son Do	(b) (4) 20 Jan 2021 16:04:46

US3642072

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:12:20

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	23 Apr 2021 20:50:19
Signature has been broken.	(b) (4) Megan Loughran (b) (4)	22 Apr 2021 18:29:24
User entered '16 Jan 2021' reason for change: Data Entry Error	(b) (4) Megan Loughran (b) (4)	22 Apr 2021 18:29:24
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 16Jan2021 is recorded under OL-1 visit in EDC, however the same is reported under OL-1 Visit with date 26Jan2021 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 12:08:44
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 16Jan2021 is recorded under OL-1 visit in EDC, however the same is reported under OL-1 Visit with date 26Jan2021 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' answered with 'Date has been corrected in the EDC' (Site from DM).	Benjamin Hull (b) (4)	23 Feb 2021 16:08:14
User entered '26 Jan 2021' reason for change: Data Entry Error	(b) (4) Benjamin Hull (b) (4)	23 Feb 2021 16:08:02
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 16Jan2021 is recorded under OL-1 visit in EDC, however the same is reported under OL-1 Visit with date 26Jan2021 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 15:26:46
User entered '16 Jan 2021'	Son Do (b) (4)	20 Jan 2021 16:04:46

US3642072

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
User entered '15:05'	Son Do (b) (4)	20 Jan 2021 16:04:46

US3642072

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User entered '16 Jan 2021 15:05'	System	22 Apr 2021 18:29:24
User entered '26 Jan 2021 15:05'	System	23 Feb 2021 16:08:02
User entered '16 Jan 2021 15:05'	System	20 Jan 2021 16:04:46

US3642072

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:12:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: It appears PPD Central Lab has two Nasopharyngeal Swab Samples labelled as "OL-1". One with Accession No: 1F616971357 dated 16-Jan-2021 and is recorded here in EDC. However, the sample with Accession No: 1F650343497, dated 26-Jan-2021 and labelled as "OL-1" is missing in EDC. Please confirm the correct visit and reconcile and make updates in EDC and as well as in PPD Portal as appropriate. Else clarify. Thank you.' (Site from DM).		21 Apr 2021 04:26:48
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: It appears PPD Central Lab has two Nasopharyngeal Swab Samples labelled as "OL-1". One with Accession No: 1F616971357 dated 16-Jan-2021 and is recorded here in EDC. However, the sample with Accession No: 1F650343497, dated 26-Jan-2021 and labelled as "OL-1" is missing in EDC. Please confirm the correct visit and reconcile and make updates in EDC and as well as in PPD Portal as appropriate. Else clarify. Thank you.' answered with 'AWB Number: 1002286100910006408600936270976198' (Site from DM).	Benjamin Hull (b) (4) (b) (4)	09 Apr 2021 18:56:22
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: It appears PPD Central Lab has two Nasopharyngeal Swab Samples labelled as "OL-1". One with Accession No: 1F616971357 dated 16-Jan-2021 and is recorded here in EDC. However, the sample with Accession No: 1F650343497, dated 26-Jan-2021 and labelled as "OL-1" is missing in EDC. Please confirm the correct visit and reconcile and make updates in EDC and as well as in PPD Portal as appropriate. Else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 11:06:46
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	13 Feb 2021 02:37:12
User entered 'Yes (Y)'	Son Do (b) (4)	20 Jan 2021 16:04:58

US3642072

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '16 Jan 2021'	Son Do (b) (4)	20 Jan 2021 16:04:58

US3642072

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:12:20

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '15:00'	Son Do (b) (4)	20 Jan 2021 16:04:58

US3642072

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User entered '16 Jan 2021 15:00'	System	20 Jan 2021 16:04:58

US3642072

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

Form: Continuing

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Yes (Y)'	Son Do (b) (4)	20 Jan 2021 16:05:03

US3642072

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

Form: Continuing

Generated On: 10 Jun 2021 09:12:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User entered 'I'	System	20 Jan 2021 16:05:03

US3642072

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:12:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:12
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Yes (Y)'	Jennifer Morales (b) (4)	26 Jan 2021 00:54:41

US3642072

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:12:20

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:12
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '25 Jan 2021'	Jennifer Morales (b) (4)	26 Jan 2021 00:54:41

US3642072

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:12:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:12
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Contact Made (CONTACT MADE)'	Jennifer Morales (b) (4)	26 Jan 2021 00:54:41

US3642072

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:12:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:12
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered empty.	Jennifer Morales (b) (4)	26 Jan 2021 00:54:41

US3642072

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:12
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Yes (Y)'	Jennifer Morales (b) (4)	26 Jan 2021 00:54:47

US3642072

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:12:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:12
User entered 'I'	System	26 Jan 2021 00:54:47

US3642072

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:12:20

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:09:12
User entered '1'	System	26 Jan 2021 00:54:47
DataPoint set to visible.	System	26 Jan 2021 00:54:47

US3642072

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:12:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:04:27
User entered 'Yes (Y)'	Son Do (b) (4)	16 Feb 2021 16:26:36

US3642072

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:04:27
User entered '11 Feb 2021'	Son Do (b) (4)	16 Feb 2021 16:26:36

US3642072

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:12:20

[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 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:04:27
User entered 'Clinic (Clinic)'	Son Do (b) (4)	16 Feb 2021 16:26:36

US3642072

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:12:20

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User entered 'OLD29'	System	16 Feb 2021 16:26:36

US3642072

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:12:20

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User accepted default value 'Pre-Dose (PREDOSE)'	Son Do (b) (4)	16 Feb 2021 16:27:18

US3642072

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:12:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
User entered 'Yes (Y)'	Son Do (b) (4)	16 Feb 2021 16:27:18

US3642072

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:12:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
User entered '11 Feb 2021'	Son Do (b) (4)	16 Feb 2021 16:27:18

US3642072

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
User entered '14:31'	Son Do (b) (4)	16 Feb 2021 16:27:18

US3642072

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User entered '11 Feb 2021 14:31'	System	16 Feb 2021 16:27:18

US3642072

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
User entered '98.4' F	Son Do (b) (4)	16 Feb 2021 16:27:18

US3642072

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:12:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
User entered 'Oral (Oral)'	Son Do (b) (4)	16 Feb 2021 16:27:18

US3642072

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:12:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
User entered empty.	Son Do (b) (4)	16 Feb 2021 16:27:18

US3642072

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:12:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
User entered '73'	Son Do (b) (4)	16 Feb 2021 16:27:18

US3642072

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:12:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User entered 'bpm'	System	16 Feb 2021 16:27:18

US3642072

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
User entered '16'	Son Do (b) (4)	16 Feb 2021 16:27:18

US3642072

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:12:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User entered 'breaths/min'	System	16 Feb 2021 16:27:18

US3642072

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
User entered '122'	Son Do (b) (4)	16 Feb 2021 16:27:18

US3642072

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:12:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User entered 'mmHg'	System	16 Feb 2021 16:27:18

US3642072

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:12:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 09:51:38
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'BP not clinically significant.' (Site from System).	Benjamin Hull (b) (4) (b) (4)	04 Mar 2021 19:19:16
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		16 Feb 2021 16:27:18
User entered '56'	Son Do (b) (4)	16 Feb 2021 16:27:18

US3642072

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:12:20

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User entered 'mmHg'	System	16 Feb 2021 16:27:18

US3642072

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:12:20

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User accepted default value 'Post-Dose (POSTDOSE)'	Son Do (b) (4)	16 Feb 2021 16:27:18

US3642072

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:12:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
User entered 'Yes (Y)'	Son Do (b) (4)	16 Feb 2021 16:27:18

US3642072

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:12:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
User entered '11 Feb 2021'	Son Do (b) (4)	16 Feb 2021 16:27:18

US3642072

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
User entered '16:11'	Son Do (b) (4)	16 Feb 2021 16:27:18

US3642072

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User entered '11 Feb 2021 16:11'	System	16 Feb 2021 16:27:18

US3642072

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
User entered '98.4' F	Son Do (b) (4)	16 Feb 2021 16:27:18

US3642072

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:12:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
User entered 'Oral (Oral)'	Son Do (b) (4)	16 Feb 2021 16:27:18

US3642072

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:12:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
User entered empty.	Son Do (b) (4)	16 Feb 2021 16:27:18

US3642072

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:12:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
User entered '65'	Son Do (b) (4)	16 Feb 2021 16:27:18

US3642072

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:12:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User entered 'bpm'	System	16 Feb 2021 16:27:18

US3642072

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
User entered '16'	Son Do (b) (4)	16 Feb 2021 16:27:18

US3642072

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:12:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User entered 'breaths/min'	System	16 Feb 2021 16:27:18

US3642072

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
User entered '127'	Son Do (b) (4)	16 Feb 2021 16:27:18

US3642072

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:12:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User entered 'mmHg'	System	16 Feb 2021 16:27:18

US3642072

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:12:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 09:51:47
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'BP not clinically significant.' (Site from System).	Benjamin Hull (b) (4) (b) (4)	04 Mar 2021 19:19:22
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		16 Feb 2021 16:27:18
User entered '58'	Son Do (b) (4)	16 Feb 2021 16:27:18

US3642072

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:12:20

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User entered 'mmHg'	System	16 Feb 2021 16:27:18

US3642072

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:12:20

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:04:27
User entered 'No (N)'	Son Do (b) (4)	16 Feb 2021 16:27:35

US3642072

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:12:20

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:04:27
User entered empty.	Son Do (b) (4)	16 Feb 2021 16:27:35

US3642072

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:12:20

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User closed query 'Per CDM: Open Label Day 29 date is not present in IRT. Please update IRT else clarify. ' (Site from DM).		16 Apr 2021 13:59:26
Query 'Per CDM: Open Label Day 29 date is not present in IRT. Please update IRT else clarify. ' answered with 'this participant was inadvertently unblinded prior to amendment 6. this was an error on the site's part. We received permission to retain the participant in study and enter her into the OL phase. A dcf was submitted per monitor instructions in order to get her back into the IRT system, however, because she was unblinded, her PID never re-populated into the IRT system. We are unable to record a visit for this participant because she is not listed as a pending participant in IRT. The pharmacy was able to manually dispense study drug so the participant did receive vaccination, but we are unable to reconcile in irt. ' (Site from DM).	Megan Loughran (b) (4) (b) (4)	14 Apr 2021 19:15:58
User opened query 'Per CDM: Open Label Day 29 date is not present in IRT. Please update IRT else clarify. ' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 09:16:34
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	19 Feb 2021 21:04:27
User entered 'Yes (Y)'	Son Do (b) (4)	16 Feb 2021 16:27:53

US3642072

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:12:20

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:04:27
User entered empty.	Son Do (b) (4)	16 Feb 2021 16:27:53

US3642072

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:04:27
User entered empty.	Son Do (b) (4)	16 Feb 2021 16:27:53

US3642072

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:12:20

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User entered 'mRNA-1273'	System	16 Feb 2021 16:27:53
DataPoint set to visible.	System	26 Jan 2021 00:54:47

US3642072

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:12:20

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:04:27
User entered '11 Feb 2021'	Son Do (b) (4)	16 Feb 2021 16:27:53

US3642072

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:04:27
User entered '15:40'	Son Do (b) (4)	16 Feb 2021 16:27:53

US3642072

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User entered '11 Feb 2021 15:40'	System	16 Feb 2021 16:27:53

US3642072

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:04:27
User entered 'Left Arm (LEFT ARM)'	Son Do (b) (4)	16 Feb 2021 16:27:53

US3642072

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User entered 'ONCE'	System	16 Feb 2021 16:27:53

US3642072

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User entered 'INTRAMUSCULAR'	System	16 Feb 2021 16:27:53

US3642072

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:04:27
User entered 'Yes (Y)'	Son Do (b) (4)	16 Feb 2021 16:28:07

US3642072

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:12:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:13:52
User entered 'I'	System	16 Feb 2021 16:28:07

US3642072

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:12:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:08:18
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:04:27
User entered 'Yes (Y)'	Jennifer Morales (b) (4)	18 Feb 2021 18:32:43

US3642072

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:12:20

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:08:18
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:04:27
User entered '18 Feb 2021'	Jennifer Morales (b) (4)	18 Feb 2021 18:32:43

US3642072

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:12:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:08:18
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:04:27
User entered 'Contact Made (CONTACT MADE)'	Jennifer Morales (b) (4)	18 Feb 2021 18:32:43

US3642072

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:12:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:08:18
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:04:27
User entered empty.	Jennifer Morales (b) (4)	18 Feb 2021 18:32:43

US3642072

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:08:18
User signature succeeded.	Stephen Spector (b) (4)	19 Feb 2021 21:04:27
User entered 'Yes (Y)'	Jennifer Morales (b) (4)	18 Feb 2021 18:32:49

US3642072

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:12:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:08:18
User entered 'I'	System	18 Feb 2021 18:32:49

US3642072

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:12:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:17
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:16:54
User entered 'Yes (Y)'	Son Do (b) (4)	24 Mar 2021 15:09:03

US3642072

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:17
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:16:54
User entered '18 Mar 2021'	Son Do (b) (4)	24 Mar 2021 15:09:03

US3642072

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:17
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:16:54
User entered 'Clinic (Clinic)'	Son Do (b) (4)	24 Mar 2021 15:09:03

US3642072

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:12:20

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:17
User entered 'OLD57'	System	24 Mar 2021 15:09:03

US3642072

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:12:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:17
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:16:54
User entered 'No (N)'	Son Do (b) (4)	24 Mar 2021 15:09:10

US3642072

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:12:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:17
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:16:54
User entered empty.	Son Do (b) (4)	24 Mar 2021 15:09:10

US3642072

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:17
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:16:54
User entered empty.	Son Do (b) (4)	24 Mar 2021 15:09:10

US3642072

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:17
User entered empty.	System	24 Mar 2021 15:09:10

US3642072

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:17
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:16:54
User entered empty.	Son Do (b) (4)	24 Mar 2021 15:09:10

US3642072

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:12:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:17
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:16:54
User entered empty.	Son Do (b) (4)	24 Mar 2021 15:09:10

US3642072

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:12:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:17
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:16:54
User entered empty.	Son Do (b) (4)	24 Mar 2021 15:09:10

US3642072

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:12:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:17
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:16:54
User entered empty.	Son Do (b) (4)	24 Mar 2021 15:09:10

US3642072

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:12:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:17
User entered empty.	System	24 Mar 2021 15:09:10

US3642072

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:17
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:16:54
User entered empty.	Son Do (b) (4)	24 Mar 2021 15:09:10

US3642072

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:12:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:17
User entered empty.	System	24 Mar 2021 15:09:10

US3642072

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:17
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:16:54
User entered empty.	Son Do (b) (4)	24 Mar 2021 15:09:10

US3642072

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:12:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:17
User entered empty.	System	24 Mar 2021 15:09:10

US3642072

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:17
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:16:54
User entered empty.	Son Do (b) (4)	24 Mar 2021 15:09:10

US3642072

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:12:20

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:17
User entered empty.	System	24 Mar 2021 15:09:10

US3642072

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:12:20

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:17

US3642072

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:12:20

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:17

US3642072

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:12:20

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:17
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:16:54
User entered 'No (N)'	Son Do (b) (4)	24 Mar 2021 15:09:16

US3642072

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:12:20

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:17
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:16:54
User entered empty.	Son Do (b) (4)	24 Mar 2021 15:09:16

US3642072

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:12:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:17
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:16:54
User entered 'Yes (Y)'	Son Do (b) (4)	24 Mar 2021 15:09:29

US3642072

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:12:20

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:17
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:16:54
User entered '18 Mar 2021'	Son Do (b) (4)	24 Mar 2021 15:09:29

US3642072

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:17
User signature succeeded.	Stephen Spector (b) (4)	26 Mar 2021 21:16:54
User entered '14:15'	Son Do (b) (4)	24 Mar 2021 15:09:29

US3642072

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:32:17
User entered '18 Mar 2021 14:15'	System	24 Mar 2021 15:09:29

US3642072

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:12:20

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:13:47
User closed query 'Per DM CLR: Per Day 103, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).		02 Apr 2021 07:59:11
Query 'Per DM CLR: Per Day 103, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' answered with 'Subject's Day 103 report is in reference to the AES fall (accidental) and SAE hip fracture reported. Please see AE and SAE reported.' (Site from DM).	Nancy Tang (b) (4)	01 Apr 2021 00:23:46
User opened query 'Per DM CLR: Per Day 103, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 10:52:34
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Yes (Y)' reason for change: New Information	(b) (4) Colleen McLellan (b) (4)	02 Dec 2020 20:57:28
User entered 'No (N)'	(b) (4) Son Do (b) (4)	22 Sep 2020 16:24:43

US3642072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:12:20

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 16:46:50
User entered		
'USA-US109-2020-mRNA-1273-P301000004'	System	03 Dec 2020 16:46:47
User entered 'New'	(b) (4), (b) (6)	03 Dec 2020 16:46:47

US3642072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:12:20

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Hip fracture, LLT: Hip fracture - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Apr 2021 18:23:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Apr 2021 18:23:48
User closed query 'For coding purposes, please split HIP FRACTURE AND HIP REPLACEMENT SURGERY S/P FALL into separate entries. 1. HIP FRACTURE [S/P FALL] and 2. FALL' (Site from Coder).	(b) (4), (b) (6)	14 Mar 2021 17:17:11
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	06 Mar 2021 01:40:21
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Fractures and dislocations NEC, PT: Traumatic fracture, LLT: Traumatic fracture - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Jan 2021 11:26:03
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Jan 2021 11:26:03
Query 'For coding purposes, please split HIP FRACTURE AND HIP REPLACEMENT SURGERY S/P FALL into separate entries. 1. HIP FRACTURE [S/P FALL] and 2. FALL' answered with 'SEPARATED INTO TWO ENTRIES PER REQUEST ' (Site from Coder).	Colleen McLellan (b) (4) (b) (4)	18 Jan 2021 21:20:30
Data point term sent to Coder	System	15 Jan 2021 21:37:03
Coding entries removed.	Colleen McLellan (b) (4) (b) (4)	15 Jan 2021 21:36:37
User entered 'HIP FRACTURE S/P FALL' reason for change: Per Query Resolution	Colleen McLellan (b) (4) (b) (4)	15 Jan 2021 21:36:37
User opened query 'For coding purposes, please split HIP FRACTURE AND HIP REPLACEMENT SURGERY S/P FALL into separate entries. 1. HIP FRACTURE [S/P FALL] and 2. FALL' (Site from Coder).	(b) (4), (b) (6)	26 Dec 2020 21:03:57
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Hip fracture, LLT: Hip fracture - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Dec 2020 18:54:29

US3642072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:12:20

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. Data point term sent to Coder	Coder Import (b) (4) (b) (4) System	10 Dec 2020 18:54:29
User entered 'Hip fracture and hip replacement surgery s/p fall'	Colleen McLellan (b) (4) (b) (4)	02 Dec 2020 21:01:58 02 Dec 2020 21:01:34

US3642072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:12:20

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
	(b) (4)	
User entered 'Yes (Y)'	Colleen McLellan (b) (4)	02 Dec 2020 21:01:34
	(b) (4)	

US3642072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:12:20

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
	(b) (4)	
User entered 'No (N)'	Colleen McLellan (b) (4)	02 Dec 2020 21:01:34
	(b) (4)	

US3642072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:12:20

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
	(b) (4)	
User entered 'No (N)'	Colleen McLellan (b) (4)	02 Dec 2020 21:01:34
	(b) (4)	

US3642072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
	(b) (4)	
User entered '27 Nov 2020'	Colleen McLellan (b) (4)	02 Dec 2020 21:01:34
	(b) (4)	

US3642072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
	(b) (4)	
User entered empty.	Colleen McLellan (b) (4)	02 Dec 2020 21:01:34
	(b) (4)	

US3642072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:12:20

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Dec 2020 21:01:34

US3642072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:12:20

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
	(b) (4)	
User entered 'No (N)'	Colleen McLellan (b) (4)	02 Dec 2020 21:01:34
	(b) (4)	

US3642072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:12:20

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
	(b) (4)	
User entered '30 Nov 2020'	Colleen McLellan (b) (4)	02 Dec 2020 21:01:34
	(b) (4)	

US3642072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
	(b) (4)	
User entered empty.	Colleen McLellan (b) (4)	02 Dec 2020 21:01:34
	(b) (4)	

US3642072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:12:20

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Dec 2020 21:01:34

US3642072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:12:20

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
	(b) (4)	
User entered 'Grade 3/Severe (Grade 3/Severe)'	Colleen McLellan (b) (4)	02 Dec 2020 21:01:34
	(b) (4)	

US3642072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:12:20

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
	(b) (4)	
User entered 'Yes (Y)'	Colleen McLellan (b) (4)	02 Dec 2020 21:01:34
	(b) (4)	

US3642072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:12:20

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
	(b) (4)	
User entered '0'	Colleen McLellan (b) (4)	02 Dec 2020 21:01:34
	(b) (4)	

US3642072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:12:20

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
	(b) (4)	
User entered '0'	Colleen McLellan (b) (4)	02 Dec 2020 21:01:34
	(b) (4)	

US3642072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:12:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
	(b) (4)	
User entered '1'	Colleen McLellan (b) (4)	02 Dec 2020 21:01:34
	(b) (4)	

US3642072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:12:20

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
	(b) (4)	
User entered '27 Nov 2020'	Colleen McLellan (b) (4)	02 Dec 2020 21:01:34
	(b) (4)	

US3642072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:12:20

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
	(b) (4)	
User entered '30 Nov 2020'	Colleen McLellan (b) (4)	02 Dec 2020 21:01:34
	(b) (4)	

US3642072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:12:20

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
	(b) (4)	
User entered 'No (N)'	Colleen McLellan (b) (4)	02 Dec 2020 21:01:34
	(b) (4)	

US3642072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:12:20

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
	(b) (4)	
User entered empty.	Colleen McLellan (b) (4)	02 Dec 2020 21:01:34
	(b) (4)	

US3642072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:12:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
	(b) (4)	
User entered '0'	Colleen McLellan (b) (4)	02 Dec 2020 21:01:34
	(b) (4)	

US3642072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:12:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
	(b) (4)	
User entered '0'	Colleen McLellan (b) (4)	02 Dec 2020 21:01:34
	(b) (4)	

US3642072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:12:20

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
	(b) (4)	
User entered '0'	Colleen McLellan (b) (4)	02 Dec 2020 21:01:34
	(b) (4)	

US3642072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:12:20

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Colleen McLellan (b) (4)	02 Dec 2020 21:01:34
	(b) (4)	

US3642072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:12:20

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Colleen McLellan (b) (4)	02 Dec 2020 21:01:34
	(b) (4)	

US3642072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:12:20

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
User closed query 'Per CDM: Per CCG pg.38, If adverse event started AFTER last dose then Action taken with investigational product should be Not applicable. Kindly confirm and update appropriately. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Jan 2021 03:51:20
Query 'Per CDM: Per CCG pg.38, If adverse event started AFTER last dose then Action taken with investigational product should be Not applicable. Kindly confirm and update appropriately. Thank you' answered with 'confirmed and corrected ' (Site from DM).	Colleen McLellan (b) (4) (b) (4)	15 Jan 2021 21:32:50
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Colleen McLellan (b) (4) (b) (4)	15 Jan 2021 21:32:32
User opened query 'Per CDM: Per CCG pg.38, If adverse event started AFTER last dose then Action taken with investigational product should be Not applicable. Kindly confirm and update appropriately. Thank you' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 11:39:29
User entered 'None (NONE)'	Colleen McLellan (b) (4) (b) (4)	02 Dec 2020 21:01:34

US3642072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:12:20

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
	(b) (4)	
User entered '0'	Colleen McLellan (b) (4)	02 Dec 2020 21:01:34
	(b) (4)	

US3642072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:12:20

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, CM #8 indication is POST-SURGICAL PAIN. Please review if the AE term and CM indication should be reconciled so there will be an appropriate match. Otherwise, clarify.' (Site from DM). Query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, CM #8 indication is POST-SURGICAL PAIN. Please review if the AE term and CM indication should be reconciled so there will be an appropriate match. Otherwise, clarify.' answered with 'indication for con med line #8 has been revised to match this ae' (Site from DM).	(b) (4) (b) (4), (b) (6) Megan Loughran (b) (4) (b) (4)	24 Feb 2021 03:09:12 23 Feb 2021 16:11:16
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, CM #8 indication is POST-SURGICAL PAIN. Please review if the AE term and CM indication should be reconciled so there will be an appropriate match. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 01:40:40
User entered 'I'	Colleen McLellan (b) (4) (b) (4)	02 Dec 2020 21:01:34

US3642072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:12:20

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
	(b) (4)	
User entered 'I'	Colleen McLellan (b) (4)	02 Dec 2020 21:01:34
	(b) (4)	

US3642072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:12:20

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Colleen McLellan (b) (4)	02 Dec 2020 21:01:34
	(b) (4)	

US3642072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:12:20

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
	(b) (4)	
User entered empty.	Colleen McLellan (b) (4)	02 Dec 2020 21:01:34
	(b) (4)	

US3642072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:12:20

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
Signature has been broken.	(b) (4)	
	Colleen McLellan (b) (4)	30 Mar 2021 19:10:00
	(b) (4)	
User entered 'SUBJECT REPORTS THAT ON FRIDAY MORNING 27NOV2020 SHE FELL AND SHE DID NOT HIT HER HEAD OR LOOSE CONSCIOUSNESS (FALL ACCIDENTAL). SHE FELL WHILE WALKING AT THE BEACH AND FRACTURED HER LEFT HIP AND WAS TAKEN TO SCRIPPS GREEN HOSPITAL WHERE SHE WAS ADMITTED TO THE HOSPITAL AND UNDERWENT A HIP REPLACEMENT ON 28NOV2020. SHE WAS TESTED FOR COVID PRIOR TO SURGERY AND TESTED NEGATIVE. SHE HAS NO SIGNS OR SYMPTOMS OF COVID AT THIS TIME. SHE SAID SHE DOES NOT KNOW ANY FURTHER DETAILS BUT SHE SIGNED A MEDICAL RELEASE FORM WHEN ENROLLING SO WE ARE WELCOME TO REQUEST THE RECORDS FROM SCRIPPS. SHE IS NOW TAKING DAILY ASPIRIN 325MG DAILY. SHE WAS ALSO PRESCRIBED OXYCODONE 5MG Q4-6HOURS PRN BUT SHE REPORTS SHE IS TAKING IT ABOUT EVERY 7 HOURS.	Colleen McLellan (b) (4)	30 Mar 2021 19:10:00
	(b) (4)	
Update: patient followed up with orthopedic surgeon on 02MAR2021. All pain associated with AE resolved, pain medications discontinued. MD is happy with the patients progress and they will follow up again in approx 3 months.' reason for change:		
New Information		
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
	(b) (4)	
User closed query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event.' (Site from Safety).	(b) (4), (b) (6)	19 Jan 2021 14:29:35
User closed query 'PV Query: As the last dose of study drug was given on 23 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).		19 Jan 2021 14:29:22

US3642072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:12:20

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: #1. Please clarify whether there was loss of consciousness when a fall occurred or the fall was accidental.' (Site from Safety).	(b) (4), (b) (6)	19 Jan 2021 14:29:19
Query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event.' answered with 'UPDATED TO TWO EVENTS: FALL AND HIP FRACTURE S/P FALL ' (Site from Safety).	Colleen McLellan (b) (4)	18 Jan 2021 21:21:04
Query 'PV Query: As the last dose of study drug was given on 23 Sep 2020, please update the action taken with study drug from none to not applicable.' answered with 'UPDATED PER REQUEST' (Site from Safety).	Colleen McLellan (b) (4)	15 Jan 2021 21:35:24
User entered 'SUBJECT REPORTS THAT ON FRIDAY MORNING 27NOV2020 SHE FELL AND SHE DID NOT HIT HER HEAD OR LOOSE CONSCIOUSNESS (FALL ACCIDENTAL). SHE FELL WHILE WALKING AT THE BEACH AND FRACTURED HER LEFT HIP AND WAS TAKEN TO SCRIPPS GREEN HOSPITAL WHERE SHE WAS ADMITTED TO THE HOSPITAL AND UNDERWENT A HIP REPLACEMENT ON 28NOV2020. SHE WAS TESTED FOR COVID PRIOR TO SURGERY AND TESTED NEGATIVE. SHE HAS NO SIGNS OR SYMPTOMS OF COVID AT THIS TIME. SHE SAID SHE DOES NOT KNOW ANY FURTHER DETAILS BUT SHE SIGNED A MEDICAL RELEASE FORM WHEN ENROLLING SO WE ARE WELCOME TO REQUEST THE RECORDS FROM SCRIPPS. SHE IS NOW TAKING DAILY ASPIRIN 325MG DAILY. SHE WAS ALSO PRESCRIBED OXYCODONE 5MG Q4-6HOURS PRN BUT SHE REPORTS SHE IS TAKING IT ABOUT EVERY 7 HOURS.' reason for change: Per Query Resolution	Colleen McLellan (b) (4)	15 Jan 2021 21:35:14
Query 'PV Query: #1. Please clarify whether there was loss of consciousness when a fall occurred or the fall was accidental.' answered with 'UPDATED PER REQUEST, NO LOC, FALL ACCIDENTAL' (Site from Safety).	Colleen McLellan (b) (4)	15 Jan 2021 21:34:19

US3642072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:12:20

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT REPORTS THAT ON FRIDAY MORNING 27NOV2020, SHE DID NOT HIT HER HEAD OR LOOSE CONSCIOUSNESS. SHE FELL WHILE WALKING AT THE BEACH AND FRACTURED HER LEFT HIP AND WAS TAKEN TO SCRIPPS GREEN HOSPITAL WHERE SHE WAS ADMITTED TO THE HOSPITAL AND UNDERWENT A HIP REPLACEMENT ON 28NOV2020. SHE WAS TESTED FOR COVID PRIOR TO SURGERY AND TESTED NEGATIVE. SHE HAS NO SIGNS OR SYMPTOMS OF COVID AT THIS TIME. SHE SAID SHE DOES NOT KNOW ANY FURTHER DETAILS BUT SHE SIGNED A MEDICAL RELEASE FORM WHEN ENROLLING SO WE ARE WELCOME TO REQUEST THE RECORDS FROM SCRIPPS. SHE IS NOW TAKING DAILY ASPIRIN 325MG DAILY. SHE WAS ALSO PRESCRIBED OXYCODONE 5MG Q4-6HOURS PRN BUT SHE REPORTS SHE IS TAKING IT ABOUT EVERY 7 HOURS.' reason for change: Per Query Resolution	Colleen McLellan (b) (4)	(b) (4) 15 Jan 2021 21:33:45
User opened query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event.' (Site from Safety).	(b) (4), (b) (6)	10 Dec 2020 12:18:48
User opened query 'PV Query: As the last dose of study drug was given on 23 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).		10 Dec 2020 12:18:25
User opened query 'PV Query: #1. Please clarify whether there was loss of consciousness when a fall occurred or the fall was accidental.' (Site from Safety).		10 Dec 2020 12:17:56

US3642072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:12:20

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Subject reports that on Friday morning 27NOV2020 she fell while walking at the beach and fractured her left hip and was taken to Scripps Green Hospital where she was admitted to the hospital and underwent a hip replacement on 28NOV2020. She was tested for COVID prior to surgery and tested negative. She has no signs or symptoms of COVID at this time. She said she does not know any further details but she signed a medical release form when enrolling so we are welcome to request the records from Scripps. She is now taking daily Aspirin 325mg daily. She was also prescribed Oxycodone 5mg Q4-6hours PRN but she reports she is taking it about every 7 hours.'	Colleen McLellan (b) (4)	(b) (4) 02 Dec 2020 21:01:34

US3642072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:12:20

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Dec 2020 21:01:34

US3642072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:12:20

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 Dec 2020 21:01:34

US3642072

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:12:20

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	02 Dec 2020 21:01:34

US3642072

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:12:20

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
Reviewed for Safety.	(b) (4)	19 Jan 2021 14:31:04
User entered 'USA-US109-2020-mRNA-1273-P301000004'	(b) (4), (b) (6)	19 Jan 2021 14:31:00

US3642072

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:12:20

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Fall, LLT: Fall - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	18 Jan 2021 21:25:20
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Jan 2021 21:25:20
Data point term sent to Coder	System	18 Jan 2021 21:14:57
User entered 'FALL (ACCIDENTAL)'	Colleen McLellan (b) (4) (b) (4)	18 Jan 2021 21:14:11

US3642072

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:12:20

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
	(b) (4)	
User entered 'Yes (Y)'	Colleen McLellan (b) (4)	18 Jan 2021 21:14:11
	(b) (4)	

US3642072

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:12:20

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
	(b) (4)	
User entered 'No (N)'	Colleen McLellan (b) (4)	18 Jan 2021 21:14:11
	(b) (4)	

US3642072

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:12:20

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
	(b) (4)	
User entered 'No (N)'	Colleen McLellan (b) (4)	18 Jan 2021 21:14:11
	(b) (4)	

US3642072

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
	(b) (4)	
User entered '27 Nov 2020'	Colleen McLellan (b) (4)	18 Jan 2021 21:14:11
	(b) (4)	

US3642072

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
	(b) (4)	
User entered empty.	Colleen McLellan (b) (4)	18 Jan 2021 21:14:11
	(b) (4)	

US3642072

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:12:20

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Jan 2021 21:14:11

US3642072

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:12:20

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
	(b) (4)	
User entered 'No (N)'	Colleen McLellan (b) (4)	18 Jan 2021 21:14:11
	(b) (4)	

US3642072

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:12:20

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
	(b) (4)	
User entered '27 Nov 2020' reason for change: Data Entry Error	Colleen McLellan (b) (4)	18 Jan 2021 21:14:31
	(b) (4)	
User entered '30 Nov 2020'	Colleen McLellan (b) (4)	18 Jan 2021 21:14:11
	(b) (4)	

US3642072

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:12:20

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
	(b) (4)	
User entered empty.	Colleen McLellan (b) (4)	18 Jan 2021 21:14:11
	(b) (4)	

US3642072

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:12:20

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Jan 2021 21:14:11

US3642072

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:12:20

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
	(b) (4)	
User entered 'Grade 3/Severe (Grade 3/Severe)'	Colleen McLellan (b) (4)	18 Jan 2021 21:14:11
	(b) (4)	

US3642072

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:12:20

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	(b) (4) System	18 Jan 2021 21:18:09
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	18 Jan 2021 21:17:14
User entered 'Yes (Y)' reason for change: Data Entry Error	Colleen McLellan (b) (4) (b) (4)	18 Jan 2021 21:17:14
User entered 'No (N)'	Colleen McLellan (b) (4) (b) (4)	18 Jan 2021 21:14:11

US3642072

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:12:20

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
	(b) (4)	
User entered '0'	Colleen McLellan (b) (4)	18 Jan 2021 21:14:11
	(b) (4)	

US3642072

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:12:20

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
	(b) (4)	
User entered '0'	Colleen McLellan (b) (4)	18 Jan 2021 21:14:11
	(b) (4)	

US3642072

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:12:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4)	18 Jan 2021 21:18:28
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).	System	18 Jan 2021 21:18:28
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	18 Jan 2021 21:18:09
User entered '1' reason for change: Data Entry Error	Colleen McLellan (b) (4)	18 Jan 2021 21:18:09
User entered '0'	Colleen McLellan (b) (4)	18 Jan 2021 21:14:11

US3642072

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:12:20

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
	(b) (4)	
User entered '27 Nov 2020' reason for change: Data Entry Error	Colleen McLellan (b) (4)	18 Jan 2021 21:18:09
	(b) (4)	
User entered empty.	Colleen McLellan (b) (4)	18 Jan 2021 21:14:11
	(b) (4)	

US3642072

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:12:20

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
	(b) (4)	
User entered '30 Nov 2020' reason for change: Data Entry Error	Colleen McLellan (b) (4)	18 Jan 2021 21:18:09
	(b) (4)	
User entered empty.	Colleen McLellan (b) (4)	18 Jan 2021 21:14:11
	(b) (4)	

US3642072

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:12:20

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Colleen McLellan (b) (4)	18 Jan 2021 21:18:28
	(b) (4)	
User entered empty.	Colleen McLellan (b) (4)	18 Jan 2021 21:14:11
	(b) (4)	

US3642072

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:12:20

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
	(b) (4)	
User entered empty.	Colleen McLellan (b) (4)	18 Jan 2021 21:14:11
	(b) (4)	

US3642072

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:12:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
	(b) (4)	
User entered '0'	Colleen McLellan (b) (4)	18 Jan 2021 21:14:11
	(b) (4)	

US3642072

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:12:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
	(b) (4)	
User entered '0'	Colleen McLellan (b) (4)	18 Jan 2021 21:14:11
	(b) (4)	

US3642072

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:12:20

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
	(b) (4)	
User entered '0'	Colleen McLellan (b) (4)	18 Jan 2021 21:14:11
	(b) (4)	

US3642072

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:12:20

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Colleen McLellan (b) (4)	18 Jan 2021 21:14:11
	(b) (4)	

US3642072

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:12:20

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Colleen McLellan (b) (4)	18 Jan 2021 21:14:11
	(b) (4)	

US3642072

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:12:20

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Colleen McLellan (b) (4)	18 Jan 2021 21:14:11
	(b) (4)	

US3642072

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:12:20

None

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
User entered '0' reason for change: Data Entry Error	(b) (4)	
	Colleen McLellan (b) (4)	18 Jan 2021 21:17:14
	(b) (4)	
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	18 Jan 2021 21:14:19
User entered '1' reason for change: Data Entry Error	Colleen McLellan (b) (4)	18 Jan 2021 21:14:19
	(b) (4)	
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	18 Jan 2021 21:14:11
User entered '0'	Colleen McLellan (b) (4)	18 Jan 2021 21:14:11
	(b) (4)	

US3642072

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:12:20

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
	(b) (4)	
User entered '0'	Colleen McLellan (b) (4)	18 Jan 2021 21:14:11
	(b) (4)	

US3642072

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:12:20

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Feb 2021 03:09:58
Query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' answered with 'con procedure has been added - line number 1: left hip replacement surgery ' (Site from DM).	Megan Loughran (b) (4) (b) (4)	23 Feb 2021 16:11:52
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 01:41:07
User entered '1' reason for change: Data Entry Error	Colleen McLellan (b) (4) (b) (4)	18 Jan 2021 21:17:14
User entered '0'	Colleen McLellan (b) (4) (b) (4)	18 Jan 2021 21:14:11

US3642072

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:12:20

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Colleen McLellan (b) (4)	18 Jan 2021 21:14:11
	(b) (4)	

US3642072

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:12:20

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
	(b) (4)	
User entered empty.	Colleen McLellan (b) (4)	18 Jan 2021 21:14:11
	(b) (4)	

US3642072

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:12:20

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	06 Mar 2021 01:40:21
User entered 'SUBJECT HAD ACCIDENTAL FALL AT THE BEACH ON 27NOV2020. NO LOC. SUBJECT DID NOT HIT HEAD. HIP FRACTURE SUSTAINED AND REQUIRED SURGERY (SEE CON PROCEDURE) - SEE HIP FRACTURE AE FOR ADDITIONAL INFORMATION.' reason for change: Data Entry Error	(b) (4) Colleen McLellan (b) (4)	18 Jan 2021 21:17:14
User entered 'SUBJECT HAD ACCIDENTAL FALL AT THE BEACH ON 27NOV2020. NO LOC. SUBJECT DID NOT HIT HEAD. HIP FRACTURE SUSTAINED - SEE HIP FRACTURE AE FOR ADDITIONAL INFORMATION.'	Colleen McLellan (b) (4) (b) (4)	18 Jan 2021 21:14:11

US3642072

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:12:20

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Jan 2021 21:17:14
User entered '0'	System	18 Jan 2021 21:14:11

US3642072

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:12:20

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	18 Jan 2021 21:14:11

US3642072

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:12:20

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	18 Jan 2021 21:18:28

US3642072

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:12:20

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:26:50

US3642072

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:12:20

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:26:50
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:19
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Cornification and dystrophic skin disorders, HLT: Skin preneoplastic conditions NEC, PT: Precancerous skin lesion, LLT: Precancerous skin lesion - version MedDRA\\23.0.	Coder Import (b) (4)	19 Mar 2021 09:45:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	19 Mar 2021 09:45:48
Data point term sent to Coder	System	18 Mar 2021 21:28:38
User entered 'PRE-BASAL CELL CARCINOMA SKIN LESION'	(b) (4), (b) (6)	18 Mar 2021 21:27:52

US3642072

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:12:20

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:26:50
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:27:52

US3642072

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:12:20

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:26:50
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:27:52

US3642072

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:12:20

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:26:50
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:27:52

US3642072

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:26:50
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:19
User entered '4 Mar 2021'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:27:52

US3642072

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:26:50
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:19
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:27:52

US3642072

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:12:20

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:26:50
User entered empty.	System	18 Mar 2021 21:27:52

US3642072

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:12:20

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:26:50
User signature succeeded.	Stephen Spector (b) (4)	28 Apr 2021 21:21:10
Signature has been broken.	Colleen McLellan (b) (4)	27 Apr 2021 17:46:50
User entered 'No (N)' reason for change: New Information	Colleen McLellan (b) (4)	27 Apr 2021 17:46:50
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Mar 2021 21:27:52

US3642072

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:12:20

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:26:50
User signature succeeded.	Stephen Spector (b) (4)	28 Apr 2021 21:21:10
Signature has been broken.	Colleen McLellan (b) (4)	27 Apr 2021 17:46:50
User entered '16 Mar 2021' reason for change: New Information	Colleen McLellan (b) (4)	27 Apr 2021 17:46:50
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:19
User entered empty.	(b) (4), (b) (6)	18 Mar 2021 21:27:52

US3642072

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:26:50
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:19
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:27:52

US3642072

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:12:20

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:26:50
User entered empty.	System	18 Mar 2021 21:27:52

US3642072

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:12:20

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:26:50
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:19
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:27:52

US3642072

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:12:20

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:26:50
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:27:52

US3642072

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:12:20

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:26:50
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:19
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:27:52

US3642072

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:12:20

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:26:50
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:19
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:27:52

US3642072

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:12:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:26:50
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:19
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:27:52

US3642072

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:12:20

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:26:50
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:19
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:27:52

US3642072

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:12:20

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:26:50
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:19
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:27:52

US3642072

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:12:20

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:26:50
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:19
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:27:52

US3642072

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:12:20

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:26:50
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:19
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:27:52

US3642072

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:12:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:26:50
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:19
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:27:52

US3642072

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:12:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:26:50
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:19
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:27:52

US3642072

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:12:20

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:26:50
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:19
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:27:52

US3642072

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:12:20

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:26:50
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:19
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:27:52

US3642072

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:12:20

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:26:50
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:19
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:27:52

US3642072

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:12:20

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:26:50
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:19
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:27:52

US3642072

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:12:20

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:26:50
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:19
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:27:52

US3642072

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:12:20

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:26:50
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:19
User entered 'I'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:27:52

US3642072

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:12:20

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:26:50
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:19
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:27:52

US3642072

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:12:20

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:26:50
User signature succeeded.	Stephen Spector (b) (4)	28 Apr 2021 21:21:10
Signature has been broken.	Colleen McLellan (b) (4)	27 Apr 2021 17:46:50
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Colleen McLellan (b) (4)	27 Apr 2021 17:46:50
New Information	(b) (4)	
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:19
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	18 Mar 2021 21:27:52

US3642072

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:12:20

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:26:50
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:19
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:27:52

US3642072

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:12:20

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:26:50
User signature succeeded.	Stephen Spector (b) (4)	28 Apr 2021 21:21:10
Signature has been broken.	(b) (4) Colleen McLellan (b) (4)	27 Apr 2021 17:46:50
User entered 'PATIENT SEEN BY THEIR DERMATOLOGIST ON 04MAR2021 DUE TO A SMALL SKIN LESION ON THEIR CHEST. THE SKIN LESION WAS THEN DIAGNOSED AS PRE-BASAL CELL CARCINOMA. THE SUBJECT WAS PRESCRIBED A MEDICATED CREAM TO APPLY. FLUOROURACIL (EFUDEX) 5% APPLIED TOPICALLY ONCE DAILY FOR TWO WEEKS FOR PRE-BASAL CELL CARCINOMA SKIN LESION STARTING ON 04MAR2021 AND STOPPED ON 16MAR2021. SUBJECT WILL FOLLOW UP WITH DERMATOLOGY ON 24MAR2021. UPDATE: PATIENT REPORTS LESION WAS RESOLVED AFTER COMPLETING FLUOROURACIL TREATMENT. SHE FOLLOWED UP WITH DERM ON 24MAR2021 WHO AGREED LESION IS RESOLVED. SHE WILL CONTINUE WITH ROUTINE DERM FOLLOW-UP, NEXT SCHEDULED SEPT2021.' reason for change: New Information	Colleen McLellan (b) (4) (b) (4)	27 Apr 2021 17:46:50
User signature succeeded.	Stephen Spector (b) (4)	19 Mar 2021 23:55:19
User entered 'PATIENT SEEN BY THEIR DERMATOLOGIST ON 04MAR2021 DUE TO A SMALL SKIN LESION ON THEIR CHEST. THE SKIN LESION WAS THEN DIAGNOSED AS PRE-BASAL CELL CARCINOMA. THE SUBJECT WAS PRESCRIBED A MEDICATED CREAM TO APPLY. FLUOROURACIL (EFUDEX) 5% APPLIED TOPICALLY ONCE DAILY FOR TWO WEEKS FOR PRE-BASAL CELL CARCINOMA SKIN LESION STARTING ON 04MAR2021 AND STOPPED ON 16MAR2021. SUBJECT WILL FOLLOW UP WITH DERMATOLOGY ON 24MAR2021.'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:27:52

US3642072

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:12:20

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:26:50
User entered '0'	System	18 Mar 2021 21:27:52

US3642072

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:12:20

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:26:50
User entered 'I'	System	18 Mar 2021 21:27:52

US3642072

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:12:20

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:26:50

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:12:20

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:13:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Yes (Y)'	Son Do (b) (4)	22 Sep 2020 16:22:13

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:12:20

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	22 Sep 2020 16:24:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 16:24:42
Data point term sent to Coder	System	22 Sep 2020 16:23:39
User entered 'levothyroxine'	Son Do (b) (4)	22 Sep 2020 16:22:56

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:12:20

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
	(b) (4)	
User entered 'No (N)'	Son Do (b) (4)	22 Sep 2020 16:22:56

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:12:20

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered 'hypothyroidism'	(b) (4) Son Do (b) (4)	22 Sep 2020 16:22:56

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:12:20

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered '75'	(b) (4) Son Do (b) (4)	22 Sep 2020 16:22:56

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:12:20

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
	(b) (4)	
User entered 'Other (OTHER)'	Son Do (b) (4)	22 Sep 2020 16:22:56

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:12:20

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered 'mcg'	(b) (4) Son Do (b) (4)	22 Sep 2020 16:22:56

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:12:20

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered 'once daily (QD)'	(b) (4) Son Do (b) (4)	22 Sep 2020 16:22:56

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:12:20

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered empty.	(b) (4) Son Do (b) (4)	22 Sep 2020 16:22:56

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:12:20

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered 'Oral (ORAL)'	(b) (4) Son Do (b) (4)	22 Sep 2020 16:22:56

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:12:20

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered empty.	(b) (4) Son Do (b) (4)	22 Sep 2020 16:22:56

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered 'UN UNK 2017'	(b) (4) Son Do (b) (4)	22 Sep 2020 16:22:56

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:12:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
	(b) (4)	
User entered '0'	Son Do (b) (4)	22 Sep 2020 16:22:56

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:12:20

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered 'Yes (Y)'	(b) (4) Son Do (b) (4)	22 Sep 2020 16:22:56

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered empty.	(b) (4) Son Do (b) (4)	22 Sep 2020 16:22:56

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:12:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
	(b) (4)	
User entered 'No (N)'	Son Do (b) (4)	22 Sep 2020 16:22:56

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:12:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 16:22:56

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:12:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 16:22:56

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:12:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Sep 2020 16:22:56

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:12:20

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	22 Sep 2020 16:24:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 16:24:42
Data point term sent to Coder	System	22 Sep 2020 16:23:39
User entered 'losartan'	Son Do (b) (4)	22 Sep 2020 16:23:25

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:12:20

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered 'No (N)'	(b) (4) Son Do (b) (4)	22 Sep 2020 16:23:25

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:12:20

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered 'hypertension'	(b) (4) Son Do (b) (4)	22 Sep 2020 16:23:25

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:12:20

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered '50'	(b) (4) Son Do (b) (4)	22 Sep 2020 16:23:25

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:12:20

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered 'mg (mg)'	(b) (4) Son Do (b) (4)	22 Sep 2020 16:23:25

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:12:20

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered empty.	(b) (4) Son Do (b) (4)	22 Sep 2020 16:23:25

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:12:20

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered 'once daily (QD)'	(b) (4) Son Do (b) (4)	22 Sep 2020 16:23:25

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:12:20

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered empty.	(b) (4) Son Do (b) (4)	22 Sep 2020 16:23:25

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:12:20

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered 'Oral (ORAL)'	(b) (4) Son Do (b) (4)	22 Sep 2020 16:23:25

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:12:20

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered empty.	(b) (4) Son Do (b) (4)	22 Sep 2020 16:23:25

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered 'UN UNK 2017'	(b) (4) Son Do (b) (4)	22 Sep 2020 16:23:25

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:12:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered '0'	(b) (4) Son Do (b) (4)	22 Sep 2020 16:23:25

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:12:20

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered 'Yes (Y)'	(b) (4) Son Do (b) (4)	22 Sep 2020 16:23:25

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:12:20

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered empty.	(b) (4) Son Do (b) (4)	22 Sep 2020 16:23:25

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:12:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered 'No (N)'	(b) (4) Son Do (b) (4)	22 Sep 2020 16:23:25

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:12:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 16:23:25

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:12:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 16:23:25

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:12:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Sep 2020 16:23:25

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:12:20

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN, PRODUCTSYNONYM: LIPITOR [ATORVASTATIN] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	22 Sep 2020 16:25:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 16:25:45
Data point term sent to Coder	System	22 Sep 2020 16:24:42
User entered 'lipitor'	Son Do (b) (4)	22 Sep 2020 16:24:05

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:12:20

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
	(b) (4)	
User entered 'No (N)'	Son Do (b) (4)	22 Sep 2020 16:24:05

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:12:20

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered 'high cholesterol'	(b) (4) Son Do (b) (4)	22 Sep 2020 16:24:05

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:12:20

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered '40'	(b) (4) Son Do (b) (4)	22 Sep 2020 16:24:05

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:12:20

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered 'mg (mg)'	(b) (4) Son Do (b) (4)	22 Sep 2020 16:24:05

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:12:20

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered empty.	(b) (4) Son Do (b) (4)	22 Sep 2020 16:24:05

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:12:20

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered 'once daily (QD)'	(b) (4) Son Do (b) (4)	22 Sep 2020 16:24:05

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:12:20

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered empty.	(b) (4) Son Do (b) (4)	22 Sep 2020 16:24:05

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:12:20

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered 'Oral (ORAL)'	(b) (4) Son Do (b) (4)	22 Sep 2020 16:24:05

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:12:20

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered empty.	(b) (4) Son Do (b) (4)	22 Sep 2020 16:24:05

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered 'UN UNK 2017'	(b) (4) Son Do (b) (4)	22 Sep 2020 16:24:05

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:12:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered '0'	(b) (4) Son Do (b) (4)	22 Sep 2020 16:24:05

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:12:20

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered 'Yes (Y)'	(b) (4) Son Do (b) (4)	22 Sep 2020 16:24:05

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:12:20

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered empty.	(b) (4) Son Do (b) (4)	22 Sep 2020 16:24:05

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:12:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered 'No (N)'	(b) (4) Son Do (b) (4)	22 Sep 2020 16:24:05

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:12:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 16:24:05

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:12:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 16:24:05

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:12:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Sep 2020 16:24:05

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:12:20

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: CARBAMIC ACID ESTERS, PRODUCT: METHOCARBAMOL, PRODUCTSYNONYM: ROBAXIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	22 Sep 2020 16:25:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 16:25:44
Data point term sent to Coder	System	22 Sep 2020 16:24:40
User entered 'robaxin'	Son Do (b) (4)	22 Sep 2020 16:24:34

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:12:20

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
	(b) (4)	
User entered 'No (N)'	Son Do (b) (4)	22 Sep 2020 16:24:34

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:12:20

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered 'bone pain'	(b) (4) Son Do (b) (4)	22 Sep 2020 16:24:34

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:12:20

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered '500'	(b) (4) Son Do (b) (4)	22 Sep 2020 16:24:34

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:12:20

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered 'mg (mg)'	(b) (4) Son Do (b) (4)	22 Sep 2020 16:24:34

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:12:20

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered empty.	(b) (4) Son Do (b) (4)	22 Sep 2020 16:24:34

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:12:20

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered 'once daily (QD)'	(b) (4) Son Do (b) (4)	22 Sep 2020 16:24:34

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:12:20

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered empty.	(b) (4) Son Do (b) (4)	22 Sep 2020 16:24:34

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:12:20

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered 'Oral (ORAL)'	(b) (4) Son Do (b) (4)	22 Sep 2020 16:24:34

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:12:20

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered empty.	(b) (4) Son Do (b) (4)	22 Sep 2020 16:24:34

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered 'UN UNK 2018'	(b) (4) Son Do (b) (4)	22 Sep 2020 16:24:34

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:12:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered '0'	(b) (4) Son Do (b) (4)	22 Sep 2020 16:24:34

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:12:20

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered 'Yes (Y)'	(b) (4) Son Do (b) (4)	22 Sep 2020 16:24:34

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:12:20

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered empty.	(b) (4) Son Do (b) (4)	22 Sep 2020 16:24:34

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:12:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered 'No (N)'	(b) (4) Son Do (b) (4)	22 Sep 2020 16:24:34

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:12:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 16:24:34

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:12:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 16:24:34

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:12:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Sep 2020 16:24:34

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:12:20

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: SELECTIVE SEROTONIN (5HT1) AGONISTS, PRODUCT: SUMATRIPTAN, PRODUCTSYNONYM: IMITREX [SUMATRIPTAN] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	02 Oct 2020 16:43:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 16:43:50
Data point term sent to Coder	System	02 Oct 2020 16:43:09
User entered 'imitrex'	Son Do (b) (4)	02 Oct 2020 16:42:45

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:12:20

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
	(b) (4)	
User entered 'No (N)'	Son Do (b) (4)	02 Oct 2020 16:42:45

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:12:20

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered 'migraines'	(b) (4) Son Do (b) (4)	02 Oct 2020 16:42:45

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:12:20

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered '25'	(b) (4) Son Do (b) (4)	02 Oct 2020 16:42:45

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:12:20

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered 'mg (mg)'	(b) (4) Son Do (b) (4)	02 Oct 2020 16:42:45

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:12:20

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered empty.	(b) (4) Son Do (b) (4)	02 Oct 2020 16:42:45

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:12:20

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered 'once daily (QD)'	(b) (4) Son Do (b) (4)	02 Oct 2020 16:42:45

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:12:20

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered empty.	(b) (4) Son Do (b) (4)	02 Oct 2020 16:42:45

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:12:20

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered 'Oral (ORAL)'	(b) (4) Son Do (b) (4)	02 Oct 2020 16:42:45

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:12:20

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered empty.	(b) (4) Son Do (b) (4)	02 Oct 2020 16:42:45

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered 'UN UNK 2018'	(b) (4) Son Do (b) (4)	02 Oct 2020 16:42:45

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:12:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered '0'	(b) (4) Son Do (b) (4)	02 Oct 2020 16:42:45

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:12:20

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered 'Yes (Y)'	(b) (4) Son Do (b) (4)	02 Oct 2020 16:42:45

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered empty.	(b) (4) Son Do (b) (4)	02 Oct 2020 16:42:45

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:12:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered 'No (N)'	(b) (4) Son Do (b) (4)	02 Oct 2020 16:42:45

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:12:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 16:42:45

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:12:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 16:42:45

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:12:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Oct 2020 16:42:45

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:12:20

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:13
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Mar 2021 17:41:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Mar 2021 17:41:47
Data point term sent to Coder	System	17 Mar 2021 17:41:23
Coding entries removed.	Megan Loughran (b) (4)	17 Mar 2021 17:41:12
User entered 'FLU vaccine' reason for change: Data Entry Error	Megan Loughran (b) (4)	17 Mar 2021 17:41:12
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Jan 2021 19:00:06
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Jan 2021 19:00:06
Data point term sent to Coder	System	14 Jan 2021 18:59:49
Coding entries removed.	Benjamin Hull (b) (4)	14 Jan 2021 18:59:45
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Nov 2020 20:24:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Nov 2020 20:24:02
Data point term sent to Coder	System	19 Nov 2020 20:23:25
User entered 'Flu Shot'	Benjamin Hull (b) (4)	19 Nov 2020 20:22:37

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:12:20

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:13
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Benjamin Hull (b) (4)	14 Jan 2021 18:59:50
User entered 'No (N)'	(b) (4)	
	Benjamin Hull (b) (4)	19 Nov 2020 20:22:37
	(b) (4)	

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:12:20

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:13
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered 'prophylaxis for flu' reason for change:	(b) (4)	
Data Entry Error	Benjamin Hull (b) (4)	14 Jan 2021 18:59:45
User entered 'flu'	(b) (4)	
	Benjamin Hull (b) (4)	19 Nov 2020 20:22:37
	(b) (4)	

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:12:20

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:13
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered '0.5' reason for change: Data Entry Error	(b) (4)	
	Benjamin Hull (b) (4)	14 Jan 2021 18:59:45
User entered '1'	(b) (4)	
	Benjamin Hull (b) (4)	19 Nov 2020 20:22:37
	(b) (4)	

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:12:20

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:13
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered 'mL (mL)' reason for change: Data Entry Error	(b) (4)	
	Benjamin Hull (b) (4)	14 Jan 2021 18:59:45
User entered 'Other (OTHER)'	(b) (4)	
	Benjamin Hull (b) (4)	19 Nov 2020 20:22:37
	(b) (4)	

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:12:20

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:13
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered empty; reason for change Data Entry Error	(b) (4)	
	Benjamin Hull (b) (4)	14 Jan 2021 18:59:45
User entered 'injection'	(b) (4)	
	Benjamin Hull (b) (4)	19 Nov 2020 20:22:37
	(b) (4)	

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:12:20

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:13
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered 'once (ONCE)'	(b) (4) Benjamin Hull (b) (4)	19 Nov 2020 20:22:37

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:12:20

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:13
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered empty.	(b) (4) Benjamin Hull (b) (4) (b) (4)	19 Nov 2020 20:22:37

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:12:20

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:13
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Benjamin Hull (b) (4)	19 Nov 2020 20:22:37

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:12:20

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:13
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered empty.	(b) (4) Benjamin Hull (b) (4)	19 Nov 2020 20:22:37

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:13
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered '23 Oct 2020'	(b) (4) Benjamin Hull (b) (4)	19 Nov 2020 20:22:37

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:12:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:13
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered '0'	(b) (4) Benjamin Hull (b) (4) (b) (4)	19 Nov 2020 20:22:37

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:12:20

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:13
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered 'No (N)'	(b) (4) Benjamin Hull (b) (4)	19 Nov 2020 20:22:37

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:13
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered '23 Oct 2020'	(b) (4) Benjamin Hull (b) (4)	19 Nov 2020 20:22:37

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:12:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:13
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered 'No (N)'	(b) (4) Benjamin Hull (b) (4)	19 Nov 2020 20:22:37

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:12:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:13
User entered empty.	System	19 Nov 2020 20:22:37

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:12:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:13
User entered empty.	System	19 Nov 2020 20:22:37

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:12:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:13
User entered empty.	System	19 Nov 2020 20:22:37

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:12:20

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Dec 2020 18:09:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Dec 2020 18:09:57
Data point term sent to Coder	System	02 Dec 2020 21:04:00
User entered 'ASPIRIN'	Colleen McLellan (b) (4)	02 Dec 2020 21:03:01

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:12:20

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
	(b) (4)	
User entered 'Yes (Y)'	Colleen McLellan (b) (4)	02 Dec 2020 21:03:01
	(b) (4)	

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:12:20

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
	(b) (4)	
User entered 'DVT PROPHYLAXIS'	Colleen McLellan (b) (4)	02 Dec 2020 21:03:01
	(b) (4)	

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:12:20

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
	(b) (4)	
User entered '325'	Colleen McLellan (b) (4)	02 Dec 2020 21:03:01
	(b) (4)	

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:12:20

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
	(b) (4)	
User entered 'mg (mg)'	Colleen McLellan (b) (4)	02 Dec 2020 21:03:01
	(b) (4)	

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:12:20

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
	(b) (4)	
User entered empty.	Colleen McLellan (b) (4)	02 Dec 2020 21:03:01
	(b) (4)	

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:12:20

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
	(b) (4)	
User entered 'once daily (QD)'	Colleen McLellan (b) (4)	02 Dec 2020 21:03:01
	(b) (4)	

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:12:20

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
	(b) (4)	
User entered empty.	Colleen McLellan (b) (4)	02 Dec 2020 21:03:01
	(b) (4)	

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:12:20

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
	(b) (4)	
User entered 'Oral (ORAL)'	Colleen McLellan (b) (4)	02 Dec 2020 21:03:01
	(b) (4)	

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:12:20

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
	(b) (4)	
User entered empty.	Colleen McLellan (b) (4)	02 Dec 2020 21:03:01
	(b) (4)	

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
	(b) (4)	
User entered '28 Nov 2020'	Colleen McLellan (b) (4)	02 Dec 2020 21:03:01
	(b) (4)	

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:12:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
	(b) (4)	
User entered '0'	Colleen McLellan (b) (4)	02 Dec 2020 21:03:01
	(b) (4)	

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:12:20

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
	(b) (4)	
User entered 'Yes (Y)'	Colleen McLellan (b) (4)	02 Dec 2020 21:03:01
	(b) (4)	

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:12:20

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
	(b) (4)	
User entered empty.	Colleen McLellan (b) (4)	02 Dec 2020 21:03:01
	(b) (4)	

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:12:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
	(b) (4)	
User entered 'No (N)'	Colleen McLellan (b) (4)	02 Dec 2020 21:03:01
	(b) (4)	

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:12:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Dec 2020 21:03:01

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:12:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Dec 2020 21:03:01

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:12:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Dec 2020 21:03:01

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:12:20

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:15
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Mar 2021 12:06:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Mar 2021 12:06:38
Data point term sent to Coder	System	23 Feb 2021 16:10:51
Data point term sent to Coder	System	23 Feb 2021 16:09:49
Coding entries removed.	Megan Loughran (b) (4)	23 Feb 2021 16:09:27
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Dec 2020 13:25:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Dec 2020 13:25:50
Data point term sent to Coder	System	02 Dec 2020 21:05:01
User entered 'OXYCODONE'	Colleen McLellan (b) (4)	02 Dec 2020 21:04:01

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:12:20

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:15
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered 'No (N)'	(b) (4) Colleen McLellan (b) (4)	02 Dec 2020 21:04:01

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:12:20

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:15
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Feb 2021 03:22:55
User entered 'HIP FRACTURE s/p fall' reason for change: Per Query Resolution	Megan Loughran (b) (4) (b) (4)	23 Feb 2021 16:10:22
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' answered with 'indication revised to match ae' (Site from DM).	Megan Loughran (b) (4) (b) (4)	23 Feb 2021 16:09:41
User entered 'Hip fracture' reason for change: Data Entry Error	Megan Loughran (b) (4) (b) (4)	23 Feb 2021 16:09:27
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 12:47:40
User entered 'POST-SURGICAL PAIN'	Colleen McLellan (b) (4) (b) (4)	02 Dec 2020 21:04:01

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:12:20

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:15
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered '5'	Colleen McLellan (b) (4)	02 Dec 2020 21:04:01

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:12:20

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:15
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered 'mg (mg)'	Colleen McLellan (b) (4)	02 Dec 2020 21:04:01

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:12:20

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:15
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered empty.	Colleen McLellan (b) (4)	02 Dec 2020 21:04:01

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:12:20

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:15
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered 'as needed (PRN)'	Colleen McLellan (b) (4)	02 Dec 2020 21:04:01

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:12:20

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:15
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered empty.	Colleen McLellan (b) (4)	02 Dec 2020 21:04:01

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:12:20

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:15
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered 'Oral (ORAL)'	Colleen McLellan (b) (4)	02 Dec 2020 21:04:01

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:12:20

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:15
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered empty.	Colleen McLellan (b) (4)	02 Dec 2020 21:04:01

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:15
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered '28 Nov 2020'	Colleen McLellan (b) (4)	02 Dec 2020 21:04:01

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:12:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:15
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered '0'	Colleen McLellan (b) (4)	02 Dec 2020 21:04:01

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:12:20

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:15
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Mar 2021 00:48:49
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'per patient, medication discontinued by orthopedic surgeon on 02mar2021. All pain associated with AE has resolved.' (Site from DM).	Colleen McLellan (b) (4) (b) (4)	30 Mar 2021 19:08:13
User entered 'No (N)' reason for change: Data Entry Error	Colleen McLellan (b) (4) (b) (4)	30 Mar 2021 19:08:09
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 14:00:59
User entered 'Yes (Y)'	Colleen McLellan (b) (4) (b) (4)	02 Dec 2020 21:04:01

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:15
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered '02 Mar 2021' reason for change: Data Entry Error	(b) (4)	
	Colleen McLellan (b) (4)	30 Mar 2021 19:08:09
User entered empty.	(b) (4)	
	Colleen McLellan (b) (4)	02 Dec 2020 21:04:01
	(b) (4)	

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:12:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:15
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered 'No (N)'	Colleen McLellan (b) (4)	02 Dec 2020 21:04:01

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:12:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:15
User entered empty.	System	02 Dec 2020 21:04:01

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:12:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:15
User entered empty.	System	02 Dec 2020 21:04:01

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:12:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:15
User entered empty.	System	02 Dec 2020 21:04:01

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:12:20

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:16
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE HYDROCHLORIDE, PRODUCTSYNONYM: OXYCONTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Feb 2021 16:12:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Feb 2021 16:12:00
Data point term sent to Coder Coding entries removed.	System Megan Loughran (b) (4)	23 Feb 2021 16:11:52 23 Feb 2021 16:10:52
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE HYDROCHLORIDE, PRODUCTSYNONYM: OXYCONTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Jan 2021 16:03:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Jan 2021 16:03:20
Data point term sent to Coder	System	20 Jan 2021 16:01:36
User entered 'oxycontin'	Son Do (b) (4)	20 Jan 2021 16:00:42

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:12:20

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:16
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered 'No (N)'	Son Do (b) (4)	20 Jan 2021 16:00:42

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:12:20

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:16
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered 'left hip replacement surgery' reason for change: Data Entry Error	(b) (4)	
	Megan Loughran (b) (4)	23 Feb 2021 16:10:52
	(b) (4)	
User entered 'hip pin surgery'	Son Do (b) (4)	20 Jan 2021 16:00:42

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:12:20

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:16
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered '10'	Son Do (b) (4)	20 Jan 2021 16:00:42

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:12:20

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:16
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered 'mg (mg)'	Son Do (b) (4)	20 Jan 2021 16:00:42

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:12:20

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:16
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered empty.	Son Do (b) (4)	20 Jan 2021 16:00:42

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:12:20

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:16
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered 'as needed (PRN)'	Son Do (b) (4)	20 Jan 2021 16:00:42

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:12:20

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:16
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered empty.	Son Do (b) (4)	20 Jan 2021 16:00:42

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:12:20

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:16
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered 'Oral (ORAL)'	Son Do (b) (4)	20 Jan 2021 16:00:42

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:12:20

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:16
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered empty.	Son Do (b) (4)	20 Jan 2021 16:00:42

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:16
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered '29 Nov 2020'	Son Do (b) (4)	20 Jan 2021 16:00:42

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:12:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:16
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered '0'	Son Do (b) (4)	20 Jan 2021 16:00:42

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:12:20

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:16
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Mar 2021 00:50:04
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'per patient, medication discontinued 02mar2021 by orthopedic surgeon. All pain related to AE now resolved. ' (Site from DM).	Colleen McLellan (b) (4) (b) (4)	30 Mar 2021 19:07:23
User entered 'No (N)' reason for change: Data Entry Error	Colleen McLellan (b) (4) (b) (4)	30 Mar 2021 19:06:40
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 00:05:35
User entered 'Yes (Y)'	Son Do (b) (4)	20 Jan 2021 16:00:42

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:16
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered '2 Mar 2021' reason for change: Data Entry Error	(b) (4) Colleen McLellan (b) (4)	30 Mar 2021 19:06:40
User entered empty.	Son Do (b) (4)	20 Jan 2021 16:00:42

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:12:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:16
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
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	20 Jan 2021 16:00:52
User entered 'No (N)' reason for change: Data Entry Son Do Error	System	20 Jan 2021 16:00:52
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Jan 2021 16:00:42
User entered empty.	Son Do (b) (4)	20 Jan 2021 16:00:42

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:12:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:16
User entered empty.	System	20 Jan 2021 16:00:42

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:12:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:16
User entered empty.	System	20 Jan 2021 16:00:42

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:12:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:16
User entered empty.	System	20 Jan 2021 16:00:42

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:12:20

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:19
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: ANTINEOPLASTIC AGENTS, ATC: ANTIMETABOLITES, ATC: PYRIMIDINE ANALOGUES, PRODUCT: FLUOROURACIL, PRODUCTSYNONYM: EFUDEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 09:58:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 09:58:37
User signature succeeded.	Stephen Spector (b) (4) (b) (4)	03 Apr 2021 23:27:44
Data point term sent to Coder	System	30 Mar 2021 19:11:28
Coding entries removed.	Colleen McLellan (b) (4) (b) (4)	30 Mar 2021 19:10:50
User entered 'FLUOROURACIL 5% (EFUDEX)' reason for change: Data Entry Error	Colleen McLellan (b) (4) (b) (4)	30 Mar 2021 19:10:50
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: ANTINEOPLASTIC AGENTS, ATC: ANTIMETABOLITES, ATC: PYRIMIDINE ANALOGUES, PRODUCT: FLUOROURACIL, PRODUCTSYNONYM: EFUDEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 07:33:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 07:33:55
Data point term sent to Coder	System	18 Mar 2021 21:30:39
User entered 'FLUOROURACIL (EFUDEX)'	(b) (4), (b) (6) (b) (4)	18 Mar 2021 21:29:45

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:12:20

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:19
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:29:45

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:12:20

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:19
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered 'PRE-BASAL CELL CARCINOMA SKIN LESION'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:29:45

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:12:20

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:19
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered '1' reason for change: Data Entry Error	(b) (4) Colleen McLellan (b) (4)	30 Mar 2021 19:10:36
User entered '5'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:29:45

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:12:20

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:19
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:29:45

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:12:20

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:19
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User closed query 'Per CDM Query: Please confirm if number of application would be a better choice instead of Strength. Please note Strength can be entered into the Name of the Medication. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Apr 2021 10:57:09
Query 'Per CDM Query: Please confirm if number of application would be a better choice instead of Strength. Please note Strength can be entered into the Name of the Medication. Thank you' answered with 'number of application updated and strength added to name of medication ' (Site from DM).	Colleen McLellan (b) (4) (b) (4)	30 Mar 2021 19:11:32
User entered 'application' reason for change: Data Entry Error	Colleen McLellan (b) (4) (b) (4)	30 Mar 2021 19:10:36
User opened query 'Per CDM Query: Please confirm if number of application would be a better choice instead of Strength. Please note Strength can be entered into the Name of the Medication. Thank you' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 02:50:57
User entered '5%'	(b) (4), (b) (6)	18 Mar 2021 21:29:45

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:12:20

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:19
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:29:45

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:12:20

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:19
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:29:45

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:12:20

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:19
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered 'Topical (TOPICAL)'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:29:45

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:12:20

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:19
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:29:45

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:19
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered '4 Mar 2021'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:29:45

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:12:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:19
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:29:45

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:12:20

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:19
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:29:45

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:12:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:19
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered '16 Mar 2021'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:29:45

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:12:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:19
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 21:29:45

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:12:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:19
User entered '2'	System	18 Mar 2021 21:29:45

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:12:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:19
User entered '1'	System	18 Mar 2021 21:29:45

US3642072

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:12:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:18:19
User entered '804 (804)'	System	18 Mar 2021 21:29:45

US3642072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:12:20

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:13:47
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'Yes (Y)' reason for change: New Information	Colleen McLellan (b) (4)	02 Dec 2020 21:04:15
User entered 'No (N)'	Son Do (b) (4)	22 Sep 2020 16:22:05

US3642072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:12:20

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
	(b) (4)	
User entered '28 Nov 2020'	Colleen McLellan (b) (4)	02 Dec 2020 21:04:57
	(b) (4)	

US3642072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:12:20

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
	(b) (4)	
User entered 'LEFT HIP REPLACEMENT'	Colleen McLellan (b) (4)	02 Dec 2020 21:04:57
	(b) (4)	

US3642072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:12:20

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
	(b) (4)	
User entered 'Adverse Event (AE)'	Colleen McLellan (b) (4)	02 Dec 2020 21:04:57
	(b) (4)	

US3642072

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:12:20

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
	(b) (4)	
User entered empty.	Colleen McLellan (b) (4)	02 Dec 2020 21:04:57
	(b) (4)	

US3642072

Folder: SAE USA-US109-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:12:20

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 14:31:13
User entered 'USA-US109-2020-MRNA-1273-P301000004'	System	03 Dec 2020 16:46:47

US3642072

Folder: SAE USA-US109-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:12:20

Serious

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 14:31:13
User entered 'Yes (Y)'	System	03 Dec 2020 16:46:47

US3642072

Folder: SAE USA-US109-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:12:20

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 14:31:13
User entered 'No (N)'	System	03 Dec 2020 16:46:47

US3642072

Folder: SAE USA-US109-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:12:20

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 14:31:13
User entered 'No (N)'	System	03 Dec 2020 16:46:47

US3642072

Folder: SAE USA-US109-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:12:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 14:31:13
User entered 'Yes (Y)'	System	03 Dec 2020 16:46:47

US3642072

Folder: SAE USA-US109-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:12:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 14:31:13
User entered 'No (N)'	System	03 Dec 2020 16:46:47

US3642072

Folder: SAE USA-US109-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:12:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 14:31:13
User entered 'No (N)'	System	03 Dec 2020 16:46:47

US3642072

Folder: SAE USA-US109-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:12:20

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 14:31:13
User entered 'No (N)'	System	03 Dec 2020 16:46:47

US3642072

Folder: SAE USA-US109-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:12:20

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 14:31:13
User entered 'Stephen'	System	03 Dec 2020 16:46:47

US3642072

Folder: SAE USA-US109-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:12:20

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 14:31:13
User entered 'Spector'	System	03 Dec 2020 16:46:47

US3642072

Folder: SAE USA-US109-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:12:20

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 14:31:13
User entered 'US'	System	03 Dec 2020 16:47:19

US3642072

Folder: SAE USA-US109-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:12:20

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	31 Mar 2021 13:11:50
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
	(b) (4)	
User entered '2'	System	19 Jan 2021 14:31:27
User entered '1'	System	03 Dec 2020 16:47:19

US3642072

Folder: SAE USA-US109-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:12:20

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 14:31:13
User entered 'USA-US109-2020-MRNA-1273-P301000004'	System	03 Dec 2020 16:46:47

US3642072

Folder: SAE USA-US109-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:12:20

Serious

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 14:31:13
User entered 'Yes (Y)'	System	03 Dec 2020 16:46:47

US3642072

Folder: SAE USA-US109-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:12:20

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 14:31:13
User entered 'No (N)'	System	03 Dec 2020 16:46:47

US3642072

Folder: SAE USA-US109-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:12:20

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 14:31:13
User entered 'No (N)'	System	03 Dec 2020 16:46:47

US3642072

Folder: SAE USA-US109-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:12:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 14:31:13
User entered 'Yes (Y)'	System	03 Dec 2020 16:46:47

US3642072

Folder: SAE USA-US109-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:12:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 14:31:13
User entered 'No (N)'	System	03 Dec 2020 16:46:47

US3642072

Folder: SAE USA-US109-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:12:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 14:31:13
User entered 'No (N)'	System	03 Dec 2020 16:46:47

US3642072

Folder: SAE USA-US109-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:12:20

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 14:31:13
User entered 'No (N)'	System	03 Dec 2020 16:46:47

US3642072

Folder: SAE USA-US109-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:12:20

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 14:31:13
User entered 'Stephen'	System	03 Dec 2020 16:46:47

US3642072

Folder: SAE USA-US109-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:12:20

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 14:31:13
User entered 'Spector'	System	03 Dec 2020 16:46:47

US3642072

Folder: SAE USA-US109-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:12:20

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 14:31:13
User entered 'US'	System	03 Dec 2020 16:47:19

US3642072

Folder: SAE USA-US109-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:12:20

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	31 Mar 2021 13:11:50
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
	(b) (4)	
User entered '2'	System	19 Jan 2021 14:31:27
User entered '1'	System	03 Dec 2020 16:47:19

US3642072

Folder: SAE USA-US109-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:12:20

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '03/Dec/2020 16:47'	(b) (4) System	03 Dec 2020 16:47:19

US3642072

Folder: SAE USA-US109-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:12:20

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 14:31:13
User entered 'I'		03 Dec 2020 16:47:19

US3642072

Folder: SAE USA-US109-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:12:20

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 14:31:13
User entered 'USA-US109-2020-MRNA-1273-P301000004'	System	03 Dec 2020 16:46:47

US3642072

Folder: SAE USA-US109-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:12:20

Serious

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 14:31:13
User entered 'Yes (Y)'	System	03 Dec 2020 16:46:47

US3642072

Folder: SAE USA-US109-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:12:20

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 14:31:13
User entered 'No (N)'	System	03 Dec 2020 16:46:47

US3642072

Folder: SAE USA-US109-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:12:20

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 14:31:13
User entered 'No (N)'	System	03 Dec 2020 16:46:47

US3642072

Folder: SAE USA-US109-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:12:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 14:31:13
User entered 'Yes (Y)'	System	03 Dec 2020 16:46:47

US3642072

Folder: SAE USA-US109-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:12:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 14:31:13
User entered 'No (N)'	System	03 Dec 2020 16:46:47

US3642072

Folder: SAE USA-US109-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:12:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 14:31:13
User entered 'No (N)'	System	03 Dec 2020 16:46:47

US3642072

Folder: SAE USA-US109-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:12:20

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 14:31:13
User entered 'No (N)'	System	03 Dec 2020 16:46:47

US3642072

Folder: SAE USA-US109-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:12:20

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 14:31:13
User entered 'Stephen'	System	03 Dec 2020 16:46:47

US3642072

Folder: SAE USA-US109-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:12:20

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 14:31:13
User entered 'Spector'	System	03 Dec 2020 16:46:47

US3642072

Folder: SAE USA-US109-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:12:20

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 14:31:13
User entered 'US'	System	03 Dec 2020 16:47:19

US3642072

Folder: SAE USA-US109-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:12:20

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	31 Mar 2021 13:11:50
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
	(b) (4)	
User entered '2'	System	19 Jan 2021 14:31:27
User entered '1'	System	03 Dec 2020 16:47:19

US3642072

Folder: SAE USA-US109-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:12:20

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered '19/Jan/2021 09:31'	(b) (4) System	19 Jan 2021 14:31:27

US3642072

Folder: SAE USA-US109-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:12:20

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	31 Mar 2021 13:11:31
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
User entered 'I'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 14:31:27

US3642072

Folder: SAE USA-US109-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:12:20

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 14:31:13
User entered 'USA-US109-2020-MRNA-1273-P301000004'	System	03 Dec 2020 16:46:47

US3642072

Folder: SAE USA-US109-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:12:20

Serious

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 14:31:13
User entered 'Yes (Y)'	System	03 Dec 2020 16:46:47

US3642072

Folder: SAE USA-US109-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:12:20

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 14:31:13
User entered 'No (N)'	System	03 Dec 2020 16:46:47

US3642072

Folder: SAE USA-US109-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:12:20

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 14:31:13
User entered 'No (N)'	System	03 Dec 2020 16:46:47

US3642072

Folder: SAE USA-US109-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:12:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 14:31:13
User entered 'Yes (Y)'	System	03 Dec 2020 16:46:47

US3642072

Folder: SAE USA-US109-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:12:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 14:31:13
User entered 'No (N)'	System	03 Dec 2020 16:46:47

US3642072

Folder: SAE USA-US109-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:12:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 14:31:13
User entered 'No (N)'	System	03 Dec 2020 16:46:47

US3642072

Folder: SAE USA-US109-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:12:20

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 14:31:13
User entered 'No (N)'	System	03 Dec 2020 16:46:47

US3642072

Folder: SAE USA-US109-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:12:20

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 14:31:13
User entered 'Stephen'	System	03 Dec 2020 16:46:47

US3642072

Folder: SAE USA-US109-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:12:20

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 14:31:13
User entered 'Spector'	System	03 Dec 2020 16:46:47

US3642072

Folder: SAE USA-US109-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:12:20

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 14:31:13
User entered 'US'	System	03 Dec 2020 16:47:19

US3642072

Folder: SAE USA-US109-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 09:12:20

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	31 Mar 2021 13:11:50
User signature succeeded.	Stephen Spector (b) (4)	13 Feb 2021 02:37:12
	(b) (4)	
User entered '2'	System	19 Jan 2021 14:31:27
User entered '1'	System	03 Dec 2020 16:47:19

US3642072

Folder: SAE USA-US109-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:12:20

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered '31/Mar/2021 08:11'	(b) (4) System	31 Mar 2021 13:11:50

US3642072

Folder: SAE USA-US109-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:12:20

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Stephen Spector (b) (4)	03 Apr 2021 23:27:44
User entered 'I'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 13:11:50