

US3172469 (Prod: Suncoast Research Group LLC - ERN-PPDS)

Generated By: KC Joubran

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US3172469

Form: Participant Creation

Data signed: (b) (4) 17 Feb 2021 13:52:35

Generated On: 09 Jun 2021 15:32:09

Participant ID

US3172469

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

US3172469

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 13:52:36

Generated On: 09 Jun 2021 15:32:09

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 21 OCT 2020

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

Folder OID SCRN

US3172469

Folder: Screening

Form: Demographics

Data signed: (b) (4) 17 Feb 2021 13:52:36

Generated On: 09 Jun 2021 15:32:09

Date of Birth (MMM yyyy)	(b) (6) 1961
Age	59
Age Units	YEARS
Age (Derived)	59
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 17 Feb 2021 13:52:36

Generated On: 09 Jun 2021 15:32:09

Date of Informed Consent (*dd MMM yyyy*) 21 OCT 2020

Month and Year of Informed Consent (derived) OCT 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1

Amendment 2

Amendment 3

Amendment 4

Amendment 5

Was participant enrolled in the study? Yes
No

If No, indicate reason for screen fail

Withdrew Consent

Inclusion/Exclusion

Cohort Full

Other

If reason for screen fail is Other, specify _____

Was this participant screened previously? Yes
No

If Yes, previous participant number _____

Enrollment Trigger 1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 17 Feb 2021 13:52:36

Generated On: 09 Jun 2021 15:32:09

Did the participant meet all eligibility criteria?

Yes

No

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 17 Feb 2021 13:52:36

Generated On: 09 Jun 2021 15:32:09

Were any significant conditions reported?

Yes

No

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 17 Feb 2021 13:52:36

Generated On: 09 Jun 2021 15:32:09

Condition	BILATERAL PRESBYOPIA
Start date (dd MMM yyyy)	UN UNK 2013
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 2013
Start Year (derived)	2013
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 17 Feb 2021 13:52:36

Generated On: 09 Jun 2021 15:32:09

Condition	HEARING LOSS MILD BILATERAL
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 17 Feb 2021 13:52:36

Generated On: 09 Jun 2021 15:32:09

Condition	MILD ASTHMA
Start date (dd MMM yyyy)	UN UNK 1966
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 1966
Start Year (derived)	1966
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 17 Feb 2021 13:52:36

Generated On: 09 Jun 2021 15:32:09

Condition	ACUTE APPENDICITIS
Start date (dd MMM yyyy)	UN UNK 1982
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1982
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1982
Start Year (derived)	1982
Stop Month and Year (derived)	JAN 1982
Stop Year (derived)	1982

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 17 Feb 2021 13:52:36

Generated On: 09 Jun 2021 15:32:09

Condition	LEFT THIGH PAIN (SECONDARY TO FALL)
Start date (dd MMM yyyy)	03 SEP 2020
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)	SEP 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3172469

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 17 Feb 2021 13:52:36

Generated On: 09 Jun 2021 15:32:09

Condition	APPENDECTOMY
Start date (dd MMM yyyy)	UN UNK 1982
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1982
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1982
Start Year (derived)	1982
Stop Month and Year (derived)	JAN 1982
Stop Year (derived)	1982

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 17 Feb 2021 13:52:36

Generated On: 09 Jun 2021 15:32:09

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	21 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	14:46 (24 HR)
Vital Signs Date and Time (derived)	21 OCT 2020 14:46
Height (<i>xxx.x</i>)	174.0 cm
Weight (<i>xxx.x</i>)	76.5 kg
BMI (<i>xxx.x</i>)	25.26754 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) 17 Feb 2021 13:52:36

Generated On: 09 Jun 2021 15:32:09

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: Screening

Form: Risk of Exposure

Data signed: (b) (4) 17 Feb 2021 13:52:36

Generated On: 09 Jun 2021 15:32:09

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) 17 Feb 2021 13:52:36

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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)	True
Resides in a single family home (i.e., detached housing)	False
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 13:52:36

Generated On: 09 Jun 2021 15:32:09

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 21 OCT 2020

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

Folder OID VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 17 Feb 2021 13:52:36

Generated On: 09 Jun 2021 15:32:09

What was the date of randomization? (dd MMM yyyy) 21 OCT 2020

What was the participant's randomization number? 117730

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) 17 Feb 2021 13:52:36

Generated On: 09 Jun 2021 15:32:09

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) 17 Feb 2021 13:52:36

Generated On: 09 Jun 2021 15:32:09

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 (<i>dd MMM yyyy</i>)	21 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	14:46 (24 HR)
Vital Signs Date and Time (derived)	21 OCT 2020 14:46
Temperature (<i>xxx.x</i>)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	74 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	89 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 17 Feb 2021 13:52:36

Generated On: 09 Jun 2021 15:32:09

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (<i>dd MMM yyyy</i>)	21 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	16:59 (24 HR)
Vital Signs Date and Time (derived)	21 OCT 2020 16:59
Temperature (<i>xxx.x</i>)	36.4 C
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	66 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	83 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 13:52:36

Generated On: 09 Jun 2021 15:32:09

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

21 OCT 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 17 Feb 2021 13:52:36

Generated On: 09 Jun 2021 15:32:09

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) 21 OCT 2020

What was the treatment time? (00:00-23:59) 16:29 (24 HR)

Treatment Date and Time (derived) 21 OCT 2020 16:29

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) 17 Feb 2021 13:52:36

Generated On: 09 Jun 2021 15:32:09

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 21 OCT 2020

Collection time (*00:00-23:59*) 16:06 (24 HR)

Collection date and time (derived) 21 OCT 2020 16:06

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 17 Feb 2021 13:52:36

Generated On: 09 Jun 2021 15:32:09

Collection date (<i>dd MMM yyyy</i>)			21 OCT 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:10	21 OCT 2020 16:10
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:52:36

Generated On: 09 Jun 2021 15:32:09

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 97.6 °F

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

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

PC Time Stamp 21 OCT 2020 17:10

PC Open Date & Time 21 OCT 2020 16:49

PC Close Date & Time 21 OCT 2020 19:19

US3172469

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:32:09

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

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

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

PC Time Stamp	22 OCT 2020 04:46
PC Open Date & Time	21 OCT 2020 20:14
PC Close Date & Time	22 OCT 2020 11:59

US3172469

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

DAY 2

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.0 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	22 OCT 2020 13:03
PC Open Date & Time	22 OCT 2020 12:00
PC Close Date & Time	23 OCT 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:32:09

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.0 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	23 OCT 2020 12:02
PC Open Date & Time	23 OCT 2020 12:00
PC Close Date & Time	24 OCT 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

DAY 4

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes
No

Please record your **TEMPERATURE** in °F _____
Was any **MEDICATION TAKEN** today for pain or fever? Yes
No

Please confirm reason for pain or fever medication (may select more than one):
To **TREAT** pain or fever that has already occurred _____
To **PREVENT** pain or fever from occurring _____
PC Time Stamp _____
PC Open Date & Time 24 OCT 2020 12:00
PC Close Date & Time 25 OCT 2020 11:59

US3172469

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:32:09

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.0 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	26 OCT 2020 10:48
PC Open Date & Time	25 OCT 2020 12:00
PC Close Date & Time	26 OCT 2020 11:59

US3172469

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:32:09

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.8 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	27 OCT 2020 09:48
PC Open Date & Time	26 OCT 2020 12:00
PC Close Date & Time	27 OCT 2020 11:59

US3172469

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:32:09

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.0 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	27 OCT 2020 14:56
PC Open Date & Time	27 OCT 2020 12:00
PC Close Date & Time	28 OCT 2020 11:59

US3172469

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

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

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp

21 OCT 2020 17:11

PC Open Date & Time

21 OCT 2020 16:49

PC Close Date & Time

21 OCT 2020 19:19

US3172469

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:32:09

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	22 OCT 2020 04:47
PC Open Date & Time	21 OCT 2020 20:14
PC Close Date & Time	22 OCT 2020 11:59

US3172469

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

DAY 2

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	23 OCT 2020 08:27
PC Open Date & Time	22 OCT 2020 12:00
PC Close Date & Time	23 OCT 2020 11:59

US3172469

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

DAY 3

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	23 OCT 2020 12:02
PC Open Date & Time	23 OCT 2020 12:00
PC Close Date & Time	24 OCT 2020 11:59

US3172469

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

DAY 4

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

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

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

- Yes
- No

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

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

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3172469

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

DAY 5

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	26 OCT 2020 10:50
PC Open Date & Time	25 OCT 2020 12:00
PC Close Date & Time	26 OCT 2020 11:59

US3172469

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

DAY 6

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

27 OCT 2020 09:48

PC Open Date & Time

26 OCT 2020 12:00

PC Close Date & Time

27 OCT 2020 11:59

US3172469

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

DAY 7

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	27 OCT 2020 14:56
PC Open Date & Time	27 OCT 2020 12:00
PC Close Date & Time	28 OCT 2020 11:59

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:32:09

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

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:32:09

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

No

Yes

PC Time stamp	21 OCT 2020 17:11
PC Open Date & Time	21 OCT 2020 16:49
PC Close Date & Time	21 OCT 2020 19:19

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:32:09

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

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:32:09

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

No

Yes

PC Time stamp	22 OCT 2020 04:48
PC Open Date & Time	21 OCT 2020 20:14
PC Close Date & Time	22 OCT 2020 11:59

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:32:09

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

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:32:09

	Yes <input type="checkbox"/>
PC Time stamp	23 OCT 2020 08:28
PC Open Date & Time	22 OCT 2020 12:00
PC Close Date & Time	23 OCT 2020 11:59

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:32:09

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

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:32:09

	Yes <input type="checkbox"/>
PC Time stamp	23 OCT 2020 12:03
PC Open Date & Time	23 OCT 2020 12:00
PC Close Date & Time	24 OCT 2020 11:59

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:32:09

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

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:32:09

Yes

PC Time stamp

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:32:09

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

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:32:09

	Yes <input type="checkbox"/>
PC Time stamp	26 OCT 2020 10:50
PC Open Date & Time	25 OCT 2020 12:00
PC Close Date & Time	26 OCT 2020 11:59

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:32:09

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

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:32:09

	Yes <input type="checkbox"/>
PC Time stamp	27 OCT 2020 09:49
PC Open Date & Time	26 OCT 2020 12:00
PC Close Date & Time	27 OCT 2020 11:59

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:32:09

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

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:32:09

Yes

PC Time stamp

PC Open Date & Time

27 OCT 2020 12:00

PC Close Date & Time

28 OCT 2020 11:59

US3172469

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:52:35

Generated On: 09 Jun 2021 15:32:09

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (dd MMM yyyy) 28 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3172469

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:52:35

Generated On: 09 Jun 2021 15:32:09

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3172469

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:52:35

Generated On: 09 Jun 2021 15:32:09

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (dd MMM yyyy) 05 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3172469

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:52:35

Generated On: 09 Jun 2021 15:32:09

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3172469

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:52:35

Generated On: 09 Jun 2021 15:32:09

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (dd MMM yyyy) 13 NOV 2020

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

Comments NO VOICEMAIL SET UP.
CONTACTED SUBJECT
If Contact Not Made, please provide Comments EMERGENCY CONTACT TO
CONTACT THE SITE.

US3172469

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:52:35

Generated On: 09 Jun 2021 15:32:09

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3172469

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 13:52:36

Generated On: 09 Jun 2021 15:32:09

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 18 NOV 2020

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

Folder OID VISIT2

US3172469

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 17 Feb 2021 13:52:36

Generated On: 09 Jun 2021 15:32:09

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 (<i>dd MMM yyyy</i>)	18 NOV 2020
Time of assessment (<i>00:00-23:59</i>)	09:22 (24 HR)
Vital Signs Date and Time (derived)	18 NOV 2020 09:22
Temperature (<i>xxx.x</i>)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	59 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3172469

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 17 Feb 2021 13:52:36

Generated On: 09 Jun 2021 15:32:09

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 (<i>dd MMM yyyy</i>)	18 NOV 2020
Time of assessment (<i>00:00-23:59</i>)	11:34 (24 HR)
Vital Signs Date and Time (derived)	18 NOV 2020 11:34
Temperature (<i>xxx.x</i>)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse (<i>xxx</i>)	61 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3172469

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 13:52:36

Generated On: 09 Jun 2021 15:32:09

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

18 NOV 2020

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

US3172469

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 17 Feb 2021 13:52:36

Generated On: 09 Jun 2021 15:32:09

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) 18 NOV 2020

What was the treatment time? (00:00-23:59) 11:04 (24 HR)

Treatment Date and Time (derived) 18 NOV 2020 11:04

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

US3172469

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 13:52:36

Generated On: 09 Jun 2021 15:32:09

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 18 NOV 2020

Collection time (*00:00-23:59*) 10:47 (24 HR)

Collection date and time (derived) 18 NOV 2020 10:47

US3172469

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 17 Feb 2021 13:52:36

Generated On: 09 Jun 2021 15:32:09

Collection date (<i>dd MMM yyyy</i>)			18 NOV 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:49	18 NOV 2020 10:49
Nasopharyngeal Swab 2	No		

US3172469

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:52:36

Generated On: 09 Jun 2021 15:32:09

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3172469

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes No

Please record your **TEMPERATURE** in °F 97.7 °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	18 NOV 2020 11:41
PC Open Date & Time	18 NOV 2020 11:24
PC Close Date & Time	18 NOV 2020 13:54

US3172469

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:32:09

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 98.5 °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 18 NOV 2020 18:02
PC Open Date & Time 18 NOV 2020 14:49
PC Close Date & Time 19 NOV 2020 11:59

US3172469

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

DAY 2

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	95.3 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	19 NOV 2020 17:24
PC Open Date & Time	19 NOV 2020 12:00
PC Close Date & Time	20 NOV 2020 11:59

US3172469

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:32:09

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	95.3 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	20 NOV 2020 14:53
PC Open Date & Time	20 NOV 2020 12:00
PC Close Date & Time	21 NOV 2020 11:59

US3172469

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:32:09

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** 96.4 °F

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

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

PC Time Stamp 21 NOV 2020 14:23

PC Open Date & Time 21 NOV 2020 12:00

PC Close Date & Time 22 NOV 2020 11:59

US3172469

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:32:09

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

Please confirm reason for pain or fever medication (may select more than one):
To **TREAT** pain or fever that has already occurred
To **PREVENT** pain or fever from occurring
PC Time Stamp
PC Open Date & Time 22 NOV 2020 12:00
PC Close Date & Time 23 NOV 2020 11:59

US3172469

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:32:09

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	96.3 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	23 NOV 2020 16:24
PC Open Date & Time	23 NOV 2020 12:00
PC Close Date & Time	24 NOV 2020 11:59

US3172469

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:32:09

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	96.5 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	24 NOV 2020 17:31
PC Open Date & Time	24 NOV 2020 12:00
PC Close Date & Time	25 NOV 2020 11:59

US3172469

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

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

Please record - **PAIN AT INJECTION SITE.**
Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity
- Any use of prescription pain
reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**
Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity
- Any use of prescription pain
reliever or prevents daily activity

PC Time Stamp	18 NOV 2020 11:41
PC Open Date & Time	18 NOV 2020 11:24
PC Close Date & Time	18 NOV 2020 13:54

US3172469

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:32:09

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	18 NOV 2020 18:02
PC Open Date & Time	18 NOV 2020 14:49
PC Close Date & Time	19 NOV 2020 11:59

US3172469

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

DAY 2

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp	19 NOV 2020 17:24
PC Open Date & Time	19 NOV 2020 12:00
PC Close Date & Time	20 NOV 2020 11:59

US3172469

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

DAY 3

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp	20 NOV 2020 14:54
PC Open Date & Time	20 NOV 2020 12:00
PC Close Date & Time	21 NOV 2020 11:59

US3172469

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

DAY 4

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

21 NOV 2020 14:23

PC Open Date & Time

21 NOV 2020 12:00

PC Close Date & Time

22 NOV 2020 11:59

US3172469

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

DAY 5

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

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

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

- Yes
- No

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

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

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp

PC Open Date & Time

22 NOV 2020 12:00

PC Close Date & Time

23 NOV 2020 11:59

US3172469

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

DAY 6

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

23 NOV 2020 16:24

PC Open Date & Time

23 NOV 2020 12:00

PC Close Date & Time

24 NOV 2020 11:59

US3172469

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

DAY 7

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	24 NOV 2020 17:32
PC Open Date & Time	24 NOV 2020 12:00
PC Close Date & Time	25 NOV 2020 11:59

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:32:09

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

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:32:09

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

No

Yes

PC Time stamp	18 NOV 2020 11:42
PC Open Date & Time	18 NOV 2020 11:24
PC Close Date & Time	18 NOV 2020 13:54

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:32:09

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

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:32:09

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

No

Yes

PC Time stamp	18 NOV 2020 18:03
PC Open Date & Time	18 NOV 2020 14:49
PC Close Date & Time	19 NOV 2020 11:59

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:32:09

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

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:32:09

	Yes <input type="checkbox"/>
PC Time stamp	19 NOV 2020 17:24
PC Open Date & Time	19 NOV 2020 12:00
PC Close Date & Time	20 NOV 2020 11:59

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:32:09

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

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:32:09

	Yes <input type="checkbox"/>
PC Time stamp	20 NOV 2020 14:54
PC Open Date & Time	20 NOV 2020 12:00
PC Close Date & Time	21 NOV 2020 11:59

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:32:09

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

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:32:09

	Yes <input type="checkbox"/>
PC Time stamp	21 NOV 2020 14:24
PC Open Date & Time	21 NOV 2020 12:00
PC Close Date & Time	22 NOV 2020 11:59

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:32:09

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

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:32:09

Yes

PC Time stamp

PC Open Date & Time

22 NOV 2020 12:00

PC Close Date & Time

23 NOV 2020 11:59

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:32:09

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

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:32:09

	Yes <input type="checkbox"/>
PC Time stamp	23 NOV 2020 16:24
PC Open Date & Time	23 NOV 2020 12:00
PC Close Date & Time	24 NOV 2020 11:59

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:32:09

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

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:32:09

	Yes <input type="checkbox"/>
PC Time stamp	24 NOV 2020 17:32
PC Open Date & Time	24 NOV 2020 12:00
PC Close Date & Time	25 NOV 2020 11:59

US3172469

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:52:35

Generated On: 09 Jun 2021 15:32:09

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

US3172469

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:52:35

Generated On: 09 Jun 2021 15:32:09

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3172469

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:52:35

Generated On: 09 Jun 2021 15:32:09

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (dd MMM yyyy) 04 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

UNABLE TO CONTACT SUBJECT.
SUBJECT'S VOICEMAIL IS NOT
SET UP. SPOKE TO EMERGENCY
CONTACT #1 BUT HAS NOT
BEEN ABLE TO CONTACT
SUBJECT. EMERGENCY
CONTACT #2 WRONG NUMBER.

US3172469

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:52:35

Generated On: 09 Jun 2021 15:32:09

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3172469

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:52:35

Generated On: 09 Jun 2021 15:32:09

Was Contact Attempted? Yes
No

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

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

Comments
If Contact Not Made, please provide Comments

UNABLE TO CONTACT
SUBJECT. CONTACTED
EMERGENCY CONTACT WHO
REPORTED SUBJECT IS
HOSPITALIZED IN JACKSON
MEMORIAL HOSPITAL.

US3172469

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:52:35

Generated On: 09 Jun 2021 15:32:09

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3172469

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 13:52:36

Generated On: 09 Jun 2021 15:32:09

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) _____

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

Folder OID VISIT3

US3172469

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 17 Feb 2021 13:52:36

Generated On: 09 Jun 2021 15:32:09

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) _____

US3172469

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 13:52:36

Generated On: 09 Jun 2021 15:32:09

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.

US3172469

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 13:52:36

Generated On: 09 Jun 2021 15:32:09

Was the sample collected? Yes
No

Collection date (dd MMM yyyy) _____

Collection time (00:00-23:59) _____

Collection date and time (derived) _____

US3172469

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:52:36

Generated On: 09 Jun 2021 15:32:09

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

DAY 61

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

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

Have 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):

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

Date and time of submission 18 DEC 2020 15:35:41

Patient Cloud Open Date & Time 18 DEC 2020 00:01

Patient Cloud Close Date & Time 22 DEC 2020 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

DAY 68

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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

Date and time of submission	
Patient Cloud Open Date & Time	25 DEC 2020 00:01
Patient Cloud Close Date & Time	29 DEC 2020 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 JAN 2021 08:42:09
Patient Cloud Open Date & Time	01 JAN 2021 00:01
Patient Cloud Close Date & Time	05 JAN 2021 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 JAN 2021 08:32:35
Patient Cloud Open Date & Time	08 JAN 2021 00:01
Patient Cloud Close Date & Time	12 JAN 2021 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 JAN 2021 10:20:18
Patient Cloud Open Date & Time	15 JAN 2021 00:01
Patient Cloud Close Date & Time	19 JAN 2021 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 JAN 2021 11:31:44
Patient Cloud Open Date & Time	22 JAN 2021 00:01
Patient Cloud Close Date & Time	26 JAN 2021 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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 checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	29 JAN 2021 04:41:58
Patient Cloud Open Date & Time	29 JAN 2021 00:01
Patient Cloud Close Date & Time	02 FEB 2021 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 FEB 2021 10:18:05
Patient Cloud Open Date & Time	05 FEB 2021 00:01
Patient Cloud Close Date & Time	09 FEB 2021 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 FEB 2021 08:41:49
Patient Cloud Open Date & Time	12 FEB 2021 00:01
Patient Cloud Close Date & Time	16 FEB 2021 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 FEB 2021 09:38:36
Patient Cloud Open Date & Time	19 FEB 2021 00:01
Patient Cloud Close Date & Time	23 FEB 2021 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

DAY 131

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

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

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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2021 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 MAR 2021 12:00:42
Patient Cloud Open Date & Time	05 MAR 2021 00:01
Patient Cloud Close Date & Time	09 MAR 2021 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	14 MAR 2021 17:24:52
Patient Cloud Open Date & Time	12 MAR 2021 00:01
Patient Cloud Close Date & Time	16 MAR 2021 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 MAR 2021 15:34:23
Patient Cloud Open Date & Time	19 MAR 2021 00:01
Patient Cloud Close Date & Time	23 MAR 2021 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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	28 MAR 2021 11:14:18
Patient Cloud Open Date & Time	26 MAR 2021 00:01
Patient Cloud Close Date & Time	30 MAR 2021 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	03 APR 2021 16:20:53
Patient Cloud Open Date & Time	02 APR 2021 00:01
Patient Cloud Close Date & Time	06 APR 2021 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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 <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	13 APR 2021 15:42:11
Patient Cloud Open Date & Time	09 APR 2021 00:01
Patient Cloud Close Date & Time	13 APR 2021 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

Date and time of submission	
Patient Cloud Open Date & Time	16 APR 2021 00:01
Patient Cloud Close Date & Time	20 APR 2021 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

DAY 187

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

Date and time of submission	
Patient Cloud Open Date & Time	23 APR 2021 00:01
Patient Cloud Close Date & Time	27 APR 2021 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

DAY 194

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

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

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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

Date and time of submission	
Patient Cloud Open Date & Time	30 APR 2021 00:01
Patient Cloud Close Date & Time	04 MAY 2021 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

Please contact your study clinic immediately. Click below to confirm that you have read this 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	14 MAY 2021 00:01
Patient Cloud Close Date & Time	18 MAY 2021 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

Please contact your study clinic immediately. Click below to confirm that you have read this 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	11 JUN 2021 00:01
Patient Cloud Close Date & Time	15 JUN 2021 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

DAY 250

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

Please contact your study clinic immediately. Click below to confirm that you have read this 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	02 JUL 2021 00:01
Patient Cloud Close Date & Time	06 JUL 2021 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

DAY 264

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

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

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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

Date and time of submission	
Patient Cloud Open Date & Time	09 JUL 2021 00:01
Patient Cloud Close Date & Time	13 JUL 2021 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

DAY 271

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

DAY 278

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

Date and time of submission	
Patient Cloud Open Date & Time	23 JUL 2021 00:01
Patient Cloud Close Date & Time	27 JUL 2021 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

DAY 285

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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
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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

Please contact your study clinic immediately. Click below to confirm that you have read this 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	13 AUG 2021 00:01
Patient Cloud Close Date & Time	17 AUG 2021 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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 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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

[Patient Cloud Close Date & Time](#) 07 SEP 2021 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

DAY 327

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

DAY 334

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

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

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

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

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

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

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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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 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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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 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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

Please contact your study clinic immediately. Click below to confirm that you have read this 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	01 OCT 2021 00:01
Patient Cloud Close Date & Time	05 OCT 2021 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#) 08 OCT 2021 00:01

[Patient Cloud Close Date & Time](#) 12 OCT 2021 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

DAY 362

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

Date and time of submission	
Patient Cloud Open Date & Time	15 OCT 2021 00:01
Patient Cloud Close Date & Time	19 OCT 2021 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

DAY 369

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

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

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

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

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

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

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

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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

Date and time of submission	
Patient Cloud Open Date & Time	22 OCT 2021 00:01
Patient Cloud Close Date & Time	26 OCT 2021 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

DAY 390

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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 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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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
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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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
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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

DAY 425

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2021 00:01
Patient Cloud Close Date & Time	21 DEC 2021 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

[Patient Cloud Close Date & Time](#) 28 DEC 2021 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

Date and time of submission	
Patient Cloud Open Date & Time	31 DEC 2021 00:01
Patient Cloud Close Date & Time	04 JAN 2022 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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 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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

14 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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 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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2022 00:01
Patient Cloud Close Date & Time	25 JAN 2022 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

DAY 467

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

Please contact your study clinic immediately. Click below to confirm that you have read this 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	04 FEB 2022 00:01
Patient Cloud Close Date & Time	08 FEB 2022 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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 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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

11 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

DAY 488

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2022 00:01
Patient Cloud Close Date & Time	22 FEB 2022 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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 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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

04 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

11 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

DAY 516

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 25 MAR 2022 00:01

[Patient Cloud Close Date & Time](#) 29 MAR 2022 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

DAY 530

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

01 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

Please contact your study clinic immediately. Click below to confirm that you have read this 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	08 APR 2022 00:01
Patient Cloud Close Date & Time	12 APR 2022 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

DAY 544

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

Date and time of submission	
Patient Cloud Open Date & Time	15 APR 2022 00:01
Patient Cloud Close Date & Time	19 APR 2022 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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°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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

13 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

Date and time of submission	
Patient Cloud Open Date & Time	27 MAY 2022 00:01
Patient Cloud Close Date & Time	31 MAY 2022 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

[Patient Cloud Close Date & Time](#) 07 JUN 2022 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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 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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2022 00:01
Patient Cloud Close Date & Time	14 JUN 2022 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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 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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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 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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

DAY 621

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

01 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

08 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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
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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2022 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

[Patient Cloud Close Date & Time](#)

26 JUL 2022 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

DAY 649

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

Date and time of submission	
Patient Cloud Open Date & Time	29 JUL 2022 00:01
Patient Cloud Close Date & Time	02 AUG 2022 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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
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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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°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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 12 AUG 2022 00:01

[Patient Cloud Close Date & Time](#) 16 AUG 2022 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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
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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2022 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

DAY 684

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

Please contact your study clinic immediately. Click below to confirm that you have read this 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	02 SEP 2022 00:01
Patient Cloud Close Date & Time	06 SEP 2022 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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 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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

DAY 698

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

DAY 705

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

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

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

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

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

Fever (Temperature \geq 100.4°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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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 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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

Date and time of submission	
Patient Cloud Open Date & Time	30 SEP 2022 00:01
Patient Cloud Close Date & Time	04 OCT 2022 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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 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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2022 00:01
Patient Cloud Close Date & Time	11 OCT 2022 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

DAY 726

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

Please contact your study clinic immediately. Click below to confirm that you have read this 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	14 OCT 2022 00:01
Patient Cloud Close Date & Time	18 OCT 2022 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

DAY 733

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

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

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

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

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

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

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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2022 00:01
Patient Cloud Close Date & Time	25 OCT 2022 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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
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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

[Patient Cloud Close Date & Time](#)

01 NOV 2022 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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 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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

04 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2022 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

DAY 754

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

11 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2022 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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°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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

[Patient Cloud Close Date & Time](#)

22 NOV 2022 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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 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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

Date and time of submission	
Patient Cloud Open Date & Time	25 NOV 2022 00:01
Patient Cloud Close Date & Time	29 NOV 2022 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#) 02 DEC 2022 00:01

[Patient Cloud Close Date & Time](#) 06 DEC 2022 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

DAY 782

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

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

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

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

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

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

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

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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

[Patient Cloud Close Date & Time](#) 13 DEC 2022 23:59

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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

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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

DAY 796

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

Please contact your study clinic immediately. Click below to confirm that you have read this 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 2022 00:01
Patient Cloud Close Date & Time	27 DEC 2022 23:59

US3172469

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:32:09

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		09 MAR 2021 12:00:28

US3172469

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:52:36

Generated On: 09 Jun 2021 15:32:09

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (*dd MMM yyyy*) 14 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3172469

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:52:35

Generated On: 09 Jun 2021 15:32:09

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3172469

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 14:43:41

Generated On: 09 Jun 2021 15:32:09

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (dd MMM yyyy) 17 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3172469

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:43:41

Generated On: 09 Jun 2021 15:32:09

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3172469

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 22 Apr 2021 16:45:30

Generated On: 09 Jun 2021 15:32:09

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (dd MMM yyyy) 21 MAR 2021

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

Comments UNABLE TO CONTACT
SUBJECT. NO VOICEMAIL SET
UP. EMERGENCY CONTACT
DOES NOT ANSWER.

If Contact Not Made, please provide Comments

US3172469

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 16:45:30

Generated On: 09 Jun 2021 15:32:09

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3172469

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 22 Apr 2021 16:45:30

Generated On: 09 Jun 2021 15:32:09

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (dd MMM yyyy) 20 APR 2021

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

Comments

If Contact Not Made, please provide Comments

US3172469

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 16:45:30

Generated On: 09 Jun 2021 15:32:09

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3172469

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:32:09

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3172469

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:09

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

US3172469

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:32:09

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.

US3172469

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:32:09

Was the sample collected? Yes
No

Collection date (*dd MMM yyyy*) _____

Collection time (*00:00-23:59*) _____

Collection date and time (derived) _____

US3172469

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:09

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

US3172469

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:32:09

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"/>

US3172469

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:32:09

Generate Next COVID-19 Assessment

Yes

No

US3172469

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

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 13:52:35

Generated On: 09 Jun 2021 15:32:09

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 05 FEB 2021

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

Folder OID UNBLND_DECIDE

US3172469

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

Form: Unblinding

Data signed: (b) (4) 22 Apr 2021 16:45:30

Generated On: 09 Jun 2021 15:32:09

Date of updated informed consent (*dd MMM yyyy*) 06 JAN 2021

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

Was the participant unblinded? Yes
No

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

Date of unblinding (*dd MMM yyyy*) 05 FEB 2021

Participant randomization assignment mRNA-1273
Placebo

Actual Dose 1 mRNA-1273
Placebo
Not Administered

Actual Dose 2 mRNA-1273
Placebo
Not Administered

Will participant receive mRNA-1273? Yes
No

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3172469

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 13:52:35

Generated On: 09 Jun 2021 15:32:09

Was the sample collected? Yes
No

Collection date (*dd MMM yyyy*) 05 FEB 2021

Collection time (*00:00-23:59*) 10:07 (24 HR)

Collection date and time (derived) 05 FEB 2021 10:07

US3172469

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 17 Feb 2021 13:52:35

Generated On: 09 Jun 2021 15:32:09

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	05 FEB 2021
Collection time (<i>00:00 - 23:59</i>)	10:09
Collection Date and Time (derived)	05 FEB 2021 10:09

US3172469

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 17 Feb 2021 13:52:35

Generated On: 09 Jun 2021 15:32:09

Did the participant experience any adverse events?

Yes

No

If Yes, enter details on the Adverse Events form.

US3172469

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:09

AEID

Adverse event

WORSENING OF BASELINE
LEFT THIGH PAIN

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)

14 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes

No

If not Ongoing, end date (dd MMM yyyy)

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

Number of Days in ICU

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US3172469

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:09

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

US3172469

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:09

AEID USA-US118-2021-MRNA-1273-P30
1000006

Adverse event PROSTATE CANCER

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) 11 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes
No

If not Ongoing, end date (dd MMM yyyy)

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 True

Hospital Admission Date (dd MMM yyyy) 14 NOV 2020

Hospital Discharge Date (dd MMM yyyy) 15 JAN 2021

Admitted to ICU? Yes
No
Unknown

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:09

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

US3172469

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:09

PATIENT CAME IN FOR
DECISION VISIT OPEN - LABEL.
HE GOT THE MRNA VACCINE
AFTER UNBLINDED. NO NEED
FOR VACCINATION TODAY. HE
WAS HOSPITALIZED FROM
11/14/2020 TO 01/15/2021 DUE TO
SEVERE AND INTRACTABLE
LEFT THIGH PAIN RADIATING
TO LEFT KNEE. PER
DISCHARGE RECORDS
BROUGHT BY SUBJECT TODAY,
HE WAS DIAGNOSED WITH
PROSTATE CANCER WITH
BONE METASTASIS. HE IS
CURRENTLY ON LUPRON AND
BICALUTAMIDE FOR PROSTATE
CANCER AND OXYCODONE,
GABAPENTIN AND
DICLOFENAC TOPICAL FOR
LEFT THIGH AND KNEE PAIN.
MORE INFORMATION WILL BE
PROVIDED UPON MEDICAL
RECORDS FROM
HOSPITALIZATION ARE
RECEIVED/ REVIEWED.

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

US3172469

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:09

AEID USA-US118-2021-MRNA-1273-P30
1000006

Adverse event BONE METASTASIS
MANIFESTED BY INTRACTIBLE
LEFT THIGH PAIN RADIATION
TO LEFT KNEE

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) 11 DEC 2020

Start time (00:00-23:59) _____

AE start date and time (derived) _____

Ongoing? Yes
No

If not Ongoing, end date (dd MMM yyyy) _____

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 True

Hospital Admission Date (dd MMM yyyy) 14 NOV 2020

Hospital Discharge Date (dd MMM yyyy) 15 JAN 2021

Admitted to ICU? Yes
No

US3172469

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:09

	Unknown <input type="radio"/>
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 <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3172469

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:09

PATIENT CAME IN FOR
DECISION VISIT OPEN - LABEL.
HE GOT THE MRNA VACCINE
AFTER UNBLINDED. NO NEED
FOR VACCINATION TODAY. HE
WAS HOSPITALIZED FROM
11/14/2020 TO 01/15/2021 DUE TO
SEVERE AND INTRACTABLE
LEFT THIGH PAIN RADIATING
TO LEFT KNEE. PER
DISCHARGE RECORDS
BROUGHT BY SUBJECT TODAY,
HE WAS DIAGNOSED WITH
PROSTATE CANCER WITH
BONE METASTASIS. HE IS
CURRENTLY ON LUPRON AND
BICALUTAMIDE FOR PROSTATE
CANCER AND OXYCODONE,
GABAPENTIN AND
DICLOFENAC TOPICAL FOR
LEFT THIGH AND KNEE PAIN.
MORE INFORMATION WILL BE
PROVIDED UPON MEDICAL
RECORDS FROM
HOSPITALIZATION ARE
RECEIVED/ REVIEWED.

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

US3172469

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:09

AEID USA-US118-2021-MRNA-1273-P30
1000016

Adverse event LEFT THIGH PAIN WORSENING

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) 22 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) 12 APR 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 True

Hospital Admission Date (dd MMM yyyy) 22 MAR 2021

Hospital Discharge Date (dd MMM yyyy) 12 APR 2021

Admitted to ICU? Yes
No
Unknown

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:09

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

US3172469

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:09

SUBJECT CALLED IS REPORTING REOCCURRENCE OF LEFT THIGH PAIN WORSENING EPISODE BEING ADMITTED TO JACKSON MEMORIAL HOSPITAL WHERE HE HAS HAD A SURGICAL PROCEDURE (HE DOESN'T KNOW) AND WAS DISCHARGED ON 12APR2021. ADDITIONAL INFORMATION TO BE PROVIDED WHEN MEDICAL RECORDS ARE RECEIVED.

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

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 17 Feb 2021 13:52:35

Generated On: 09 Jun 2021 15:32:09

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

Yes

No

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

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Mar 2021 20:18:03

Generated On: 09 Jun 2021 15:32:09

Name of Medication IBUPROFEN

Prophylaxis Yes
No

Indication LEFT THIGH PAIN

Dose per administration 800

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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EAB) (1725)

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US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Mar 2021 20:18:03

Generated On: 09 Jun 2021 15:32:09

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) 14 NOV 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 12 Mar 2021 20:18:03

Generated On: 09 Jun 2021 15:32:09

Name of Medication ALBUTEROL

Prophylaxis Yes
No

Indication MILD ASTHMA

Dose per administration 90

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 4-6 HOURS, PRN

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) 12 Mar 2021 20:18:03

Generated On: 09 Jun 2021 15:32:09

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input checked="" 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 1999

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 12 Mar 2021 20:18:03

Generated On: 09 Jun 2021 15:32:09

Name of Medication DICLOFENAC

Prophylaxis Yes
No

Indication KNEE PAIN

Dose per administration 1

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify PERCENT

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) 12 Mar 2021 20:18:03

Generated On: 09 Jun 2021 15:32:09

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*) 21 JAN 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 4

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 12 Mar 2021 20:18:03

Generated On: 09 Jun 2021 15:32:09

Name of Medication LUPRON DEPOT

Prophylaxis Yes
No

Indication PROSTATE CANCER

Dose per administration 22.5

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

EVERY 3 MONTHS

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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EAB) (1725)

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US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 12 Mar 2021 20:18:03

Generated On: 09 Jun 2021 15:32:09

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*) 22 JAN 2021

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 12 Mar 2021 20:18:03

Generated On: 09 Jun 2021 15:32:09

Name of Medication OXYCODONE HCL

Prophylaxis Yes
No

Indication LEFT THIGH PAIN

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
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 12 Mar 2021 20:18:03

Generated On: 09 Jun 2021 15:32:09

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) 18 DEC 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (dd MMM yyyy) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) 3

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 12 Mar 2021 20:18:03

Generated On: 09 Jun 2021 15:32:09

Name of Medication GABAPENTIN

Prophylaxis Yes
No

Indication BILATERAL LEFT EXTREMITIES
NUMBNESS

Dose per administration 600

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)

356 of 1917

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 12 Mar 2021 20:18:03

Generated On: 09 Jun 2021 15:32:09

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)	18 DEC 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)	3
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 <input type="radio"/>
	803 <input type="radio"/>
	804 <input checked="" type="radio"/>

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 12 Mar 2021 20:18:03

Generated On: 09 Jun 2021 15:32:09

Name of Medication BICALUTAMIDE

Prophylaxis Yes
No

Indication PROSTATE CANCER

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

BEDTIME

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

PRODUCTION RELEASE (v12.003
EAB) (1725)

358 of 1917

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 12 Mar 2021 20:18:03

Generated On: 09 Jun 2021 15:32:09

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*) 18 DEC 2020

Start date completely unknown False

Ongoing? Yes
No

If not Ongoing, End date (*dd MMM yyyy*) _____

Was this medication taken for solicited event? Yes
No

Separate Dosage Number (derived) _____

Interval Dosage Unit Number (derived) _____

Interval Dosage Definition (derived) 802
803
804

US3172469

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 22 Apr 2021 16:45:30

Generated On: 09 Jun 2021 15:32:09

Were any concomitant procedures performed?

Yes

No

If yes, please complete Concomitant Procedures form.

US3172469

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 09 Jun 2021 15:32:09

Procedure/Surgery date (<i>dd MMM</i> <i>yyy</i>)	Procedure/Surgery	Indication	If indication is Other, specify
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US3172469

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:32:09

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

US3172469

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:32:09

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

US3172469

Folder: SAE USA-US118-2020-MRNA-1273-P301000012

Form: Safety Report Form

Data signed: (b) (4) 17 Feb 2021 13:52:35

Generated On: 09 Jun 2021 15:32:09

SAEID	USA-US118-2020-MRNA-1273-P30 1000012
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	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1

US3172469

Folder: SAE USA-US118-2020-MRNA-1273-P301000012

Form: Safety Report Form (1)

Data signed: (b) (4) 17 Feb 2021 13:52:35

Generated On: 09 Jun 2021 15:32:09

SAEID	USA-US118-2020-MRNA-1273-P301000012
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	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1
Date of submission (Pre-filled from custom function)	11/DEC/2020 14:12
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.	<input checked="" type="checkbox"/> True

US3172469

Folder: SAE USA-US118-2021-MRNA-1273-P301000006

Form: Safety Report Form

Data signed: (b) (4) 17 Feb 2021 13:52:35

Generated On: 09 Jun 2021 15:32:09

SAEID	USA-US118-2021-MRNA-1273-P30 1000006
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	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1

US3172469

Folder: SAE USA-US118-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Data signed: (b) (4) 17 Feb 2021 13:52:35

Generated On: 09 Jun 2021 15:32:09

SAEID USA-US118-2021-MRNA-1273-P30
1000006

Serious Yes
No

Death Yes
No

Life threatening Yes
No

Requires inpatient or prolongation of existing Hospitalization Yes
No

Persistent or significant disability or incapacity Yes
No

Congenital anomaly or birth defect Yes
No

Other medically important event Yes
No

Investigator's First Name MARK

Investigator's Last Name KUTNER

Site Address: Street _____

Site Address: City _____

Site Address: State FL

Site Address: Postal Code _____

Investigator Country US

E2B Transmit Flag (Derived/Hidden) 1

Date of submission (Pre-filled from custom function) 08/FEB/2021 13:05

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

US3172469

Folder: SAE USA-US118-2021-MRNA-1273-P301000016

Form: Safety Report Form

Data signed: (b) (4) 22 Apr 2021 16:45:30

Generated On: 09 Jun 2021 15:32:09

SAEID	USA-US118-2021-MRNA-1273-P30 1000016
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	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1

US3172469

Folder: SAE USA-US118-2021-MRNA-1273-P301000016

Form: Safety Report Form (1)

Data signed: (b) (4) 22 Apr 2021 16:45:30

Generated On: 09 Jun 2021 15:32:09

SAEID	USA-US118-2021-MRNA-1273-P301000016
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	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1
Date of submission (Pre-filled from custom function)	14/APR/2021 09:29
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.	<input checked="" type="checkbox"/> True

Audit

US3172469 (Prod: Suncoast Research Group LLC - ERN-PPDS)

US3172469

Form: Participant Creation

Generated On: 09 Jun 2021 15:32:09

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'US3172469'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Oct 2020 18:38:56

US3172469

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:32:09

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:35:55

US3172469

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '21 OCT 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Oct 2020 18:38:58

US3172469

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Clinic (Clinic)'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:35:55

US3172469

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:32:09

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User entered 'SCRN'	System	22 Oct 2020 12:35:55

US3172469

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Year of Birth(1961) recorded on this form, however same is missing in PPD Central lab. Please reconcile the data and update as appropriate. Else clarify, thank you' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 12:56:59
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Year of Birth(1961) recorded on this form, however same is missing in PPD Central lab. Please reconcile the data and update as appropriate. Else clarify, thank you' answered with 'Confirmed with lab requisition data not missing on the requisition.' (Site from DM).	Mariete Rendon (b) (4) (b) (4)	02 Nov 2020 17:19:33
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Year of Birth(1961) recorded on this form, however same is missing in PPD Central lab. Please reconcile the data and update as appropriate. Else clarify, thank you' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 08:16:50
User entered (b) (6) 1961'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Oct 2020 18:38:59

US3172469

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:32:09

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '59'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:42:51

US3172469

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:32:09

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User entered 'YEARS'	System	22 Oct 2020 12:42:51

US3172469

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:32:09

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User entered '59'	System	21 Oct 2020 20:39:20

US3172469

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:32:09

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sex (Male) recorded on this form, however same is missing in PPD Central lab. Please reconcile the data and update as appropriate. Else clarify, thank you' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 10:45:10
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sex (Male) recorded on this form, however same is missing in PPD Central lab. Please reconcile the data and update as appropriate. Else clarify, thank you' answered with 'Confirmed with lab requisition data not missing on the requisition.' (Site from DM).	Mariete Rendon (b) (4) (b) (4)	02 Nov 2020 17:19:37
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sex (Male) recorded on this form, however same is missing in PPD Central lab. Please reconcile the data and update as appropriate. Else clarify, thank you' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 08:16:56
User entered 'Male (M)'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:42:51

US3172469

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:32:09

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:42:51

US3172469

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:32:09

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '1'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:42:51

US3172469

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:32:09

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:42:51

US3172469

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:32:09

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:42:51

US3172469

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:32:09

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:42:51

US3172469

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:32:09

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:42:51

US3172469

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:32:09

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:42:51

US3172469

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:32:09

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered empty.	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:42:51

US3172469

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:32:09

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:42:51

US3172469

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:32:09

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:42:51

US3172469

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:32:09

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '21 Oct 2020'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 20:39:20

US3172469

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User entered 'Oct 2020'	System	21 Oct 2020 20:39:20

US3172469

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User entered '2020'	System	21 Oct 2020 20:39:20

US3172469

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:32:09

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Amendment 2 (2)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 20:39:20

US3172469

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 20:39:20

US3172469

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:32:09

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 20:39:20

US3172469

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:32:09

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 20:39:20

US3172469

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:32:09

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 20:39:20

US3172469

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:32:09

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Oct 2020 18:38:58

US3172469

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:32:09

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User entered '1'	System	21 Oct 2020 20:39:23

US3172469

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 20:39:23

US3172469

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:32:09

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:44:46

US3172469

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:32:09

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Presbyopia, LLT: Presbyopia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 12:46:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 12:46:42
Data point term sent to Coder	System	22 Oct 2020 12:45:47
User entered 'BILATERAL PRESBYOPIA'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:45:29

US3172469

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'UN UNK 2013'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:45:29

US3172469

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:32:09

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:45:29

US3172469

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:32:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:45:29

US3172469

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered empty.	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:45:29

US3172469

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:32:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:45:29

US3172469

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:32:09

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User entered 'Jan 2013'	System	22 Oct 2020 12:45:29

US3172469

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:32:09

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User entered '2013'	System	22 Oct 2020 12:45:29

US3172469

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User entered empty.	System	22 Oct 2020 12:45:29

US3172469

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User entered empty.	System	22 Oct 2020 12:45:29

US3172469

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:32:09

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User coded data point as SOC: Ear and labyrinth disorders, HLG: Hearing disorders, HLT: Hearing losses, PT: Deafness bilateral, LLT: Hearing loss bilateral - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 15:12:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 15:12:37
Data point term sent to Coder	System	22 Oct 2020 12:46:48
User entered 'HEARING LOSS MILD BILATERAL'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:46:10

US3172469

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'UN UNK 2015'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:46:10

US3172469

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:32:09

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:46:10

US3172469

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:32:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:46:10

US3172469

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered empty.	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:46:10

US3172469

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:32:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:46:10

US3172469

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:32:09

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User entered 'Jan 2015'	System	22 Oct 2020 12:46:10

US3172469

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:32:09

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User entered '2015'	System	22 Oct 2020 12:46:10

US3172469

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User entered empty.	System	22 Oct 2020 12:46:10

US3172469

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User entered empty.	System	22 Oct 2020 12:46:10

US3172469

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:32:09

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 15:53:20
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'concomitant medication log was updated.' (Site from DM).	Jessie Downs (b) (4) (b) (4)	11 Jan 2021 20:54:09
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 02:35:08
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 12:47:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 12:47:36
Data point term sent to Coder	System	22 Oct 2020 12:46:48
User entered 'MILD ASTHMA'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:46:29

US3172469

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'UN UNK 1966'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:46:29

US3172469

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:32:09

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:46:29

US3172469

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:32:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:46:29

US3172469

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered empty.	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:46:29

US3172469

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:32:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:46:29

US3172469

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:32:09

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User entered 'Jan 1966'	System	22 Oct 2020 12:46:29

US3172469

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:32:09

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User entered '1966'	System	22 Oct 2020 12:46:29

US3172469

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User entered empty.	System	22 Oct 2020 12:46:29

US3172469

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User entered empty.	System	22 Oct 2020 12:46:29

US3172469

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:32:09

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Appendicitis, LLT: Acute appendicitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 12:48:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 12:48:40
Data point term sent to Coder	System	22 Oct 2020 12:47:50
User entered 'ACUTE APPENDICITIS'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:46:54

US3172469

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'UN UNK 1982'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:46:54

US3172469

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:32:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:46:54

US3172469

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:32:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:46:54

US3172469

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'UN UNK 1982'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:46:54

US3172469

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:32:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:46:54

US3172469

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:32:09

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User entered 'Jan 1982'	System	22 Oct 2020 12:46:54

US3172469

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:32:09

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User entered '1982'	System	22 Oct 2020 12:46:54

US3172469

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User entered 'Jan 1982'	System	22 Oct 2020 12:46:54

US3172469

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User entered '1982'	System	22 Oct 2020 12:46:54

US3172469

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:32:09

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Pain in extremity, LLT: Pain in thigh - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Nov 2020 00:10:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Nov 2020 00:10:52
Data point term sent to Coder	System	22 Oct 2020 12:47:49
User entered 'LEFT THIGH PAIN (SECONDARY TO FALL)'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:47:45

US3172469

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '03 Sep 2020'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:47:45

US3172469

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:32:09

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:47:45

US3172469

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:32:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:47:45

US3172469

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered empty.	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:47:45

US3172469

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:32:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:47:45

US3172469

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:32:09

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User entered 'Sep 2020'	System	22 Oct 2020 12:47:45

US3172469

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:32:09

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User entered '2020'	System	22 Oct 2020 12:47:45

US3172469

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User entered empty.	System	22 Oct 2020 12:47:45

US3172469

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User entered empty.	System	22 Oct 2020 12:47:45

US3172469

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:32:09

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Large intestine therapeutic procedures, PT: Appendectomy, LLT: Appendectomy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 12:50:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 12:50:32
Data point term sent to Coder	System	22 Oct 2020 12:48:53
User entered 'APPENDECTOMY'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:48:06

US3172469

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'UN UNK 1982'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:48:06

US3172469

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:32:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:48:06

US3172469

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:32:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:48:06

US3172469

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'UN UNK 1982'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:48:06

US3172469

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:32:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:48:06

US3172469

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:32:09

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User entered 'Jan 1982'	System	22 Oct 2020 12:48:06

US3172469

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:32:09

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User entered '1982'	System	22 Oct 2020 12:48:06

US3172469

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User entered 'Jan 1982'	System	22 Oct 2020 12:48:06

US3172469

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User entered '1982'	System	22 Oct 2020 12:48:06

US3172469

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:44:01

US3172469

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '21 Oct 2020'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:44:01

US3172469

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '14:46'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:44:01

US3172469

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User entered '21 Oct 2020 14:46'	System	22 Oct 2020 12:44:01

US3172469

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:09

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '174.0' cm	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:44:01
DataPoint set to visible.	System	21 Oct 2020 20:39:23

US3172469

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '76.5' kg	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:44:01
DataPoint set to visible.	System	21 Oct 2020 20:39:23

US3172469

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User entered '25.26754'	System	22 Oct 2020 12:44:01
DataPoint set to visible.	System	21 Oct 2020 20:39:23

US3172469

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:09

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User entered 'kg/m2'	System	22 Oct 2020 12:44:01
DataPoint set to visible.	System	21 Oct 2020 20:39:23

US3172469

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:09

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:44:01

US3172469

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:09

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered empty.	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:44:01

US3172469

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:09

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered empty.	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:44:01

US3172469

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:09

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:44:01

US3172469

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:09

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User entered 'bpm'	System	22 Oct 2020 12:44:01

US3172469

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:44:01

US3172469

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User entered 'breaths/min'	System	22 Oct 2020 12:44:01

US3172469

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:09

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:44:01

US3172469

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User entered 'mmHg'	System	22 Oct 2020 12:44:01

US3172469

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:09

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:44:01

US3172469

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:09

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User entered 'mmHg'	System	22 Oct 2020 12:44:01

US3172469

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:09

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14

US3172469

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:09

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14

US3172469

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:32:09

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:44:41

US3172469

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:32:09

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered empty.	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:44:41

US3172469

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:37:09

US3172469

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:37:09

US3172469

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:37:09

US3172469

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:37:09

US3172469

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:37:09

US3172469

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:37:09

US3172469

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:37:09

US3172469

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:37:09

US3172469

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:37:09

US3172469

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:37:09

US3172469

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:37:09

US3172469

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:09

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:37:09

US3172469

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:09

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered empty.	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:37:09

US3172469

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:09

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:37:09

US3172469

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:37:09

US3172469

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:37:09

US3172469

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:37:09

US3172469

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '1'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:37:09

US3172469

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:37:09

US3172469

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:09

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '0'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:37:09

US3172469

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:32:09

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered empty.	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:37:09

US3172469

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:32:09

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:48:31

US3172469

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '21 Oct 2020'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:48:31

US3172469

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Clinic (Clinic)'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:48:31

US3172469

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:32:09

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User entered 'VISIT1'	System	22 Oct 2020 12:48:31

US3172469

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '21 OCT 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Oct 2020 19:53:36

US3172469

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '117730'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Oct 2020 19:53:36

US3172469

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Oct 2020 19:53:36

US3172469

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:32:09

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)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:48:54

US3172469

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:32:09

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)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:48:54

US3172469

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:48:54

US3172469

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:32:09

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:48:54

US3172469

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:32:09

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:48:54

US3172469

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:48:54
DataPoint set to visible.	System	21 Oct 2020 20:39:20

US3172469

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:32:09

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:51:45

US3172469

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:32:09

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:51:45

US3172469

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:32:09

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:51:45

US3172469

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:32:09

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:51:45

US3172469

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:09

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User accepted default value 'Pre-Dose (PREDOSE)'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:51:45

US3172469

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:09

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:51:45

US3172469

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '21 Oct 2020'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:51:45

US3172469

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '14:46'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:51:45

US3172469

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User entered '21 Oct 2020 14:46'	System	22 Oct 2020 12:51:45

US3172469

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:09

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '36.8' C	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:51:45

US3172469

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:09

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Oral (Oral)'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:51:45

US3172469

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:09

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered empty.	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:51:45

US3172469

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:09

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '74'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:51:45

US3172469

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:09

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User entered 'bpm'	System	22 Oct 2020 12:51:45

US3172469

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '15'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:51:45

US3172469

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User entered 'breaths/min'	System	22 Oct 2020 12:51:45

US3172469

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:09

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '130'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:51:45

US3172469

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User entered 'mmHg'	System	22 Oct 2020 12:51:45

US3172469

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:09

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '89'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:51:45

US3172469

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:09

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User entered 'mmHg'	System	22 Oct 2020 12:51:45

US3172469

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:32:09

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:51:45

US3172469

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:32:09

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:51:45

US3172469

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:09

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User accepted default value 'Post-Dose (POSTDOSE)'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:51:45

US3172469

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:09

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:51:45

US3172469

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '21 Oct 2020'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:51:45

US3172469

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '16:59'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:51:45

US3172469

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User entered '21 Oct 2020 16:59'	System	22 Oct 2020 12:51:45

US3172469

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:09

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '36.4' C	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:51:45

US3172469

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:09

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Oral (Oral)'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:51:45

US3172469

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:09

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered empty.	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:51:45

US3172469

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:09

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '66'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:51:45

US3172469

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:09

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User entered 'bpm'	System	22 Oct 2020 12:51:45

US3172469

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '14'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:51:45

US3172469

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User entered 'breaths/min'	System	22 Oct 2020 12:51:45

US3172469

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:09

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '139'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:51:45

US3172469

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User entered 'mmHg'	System	22 Oct 2020 12:51:45

US3172469

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:09

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '83'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:51:45

US3172469

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:09

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User entered 'mmHg'	System	22 Oct 2020 12:51:45

US3172469

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:32:09

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:51:50

US3172469

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:32:09

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '21 Oct 2020'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:51:50

US3172469

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:32:09

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 20:40:49

US3172469

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:32:09

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 20:40:49

US3172469

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:32:09

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)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 20:40:49

US3172469

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:32:09

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User entered 'MRNA-1273 OR PLACEBO'	System	21 Oct 2020 20:40:49

US3172469

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:32:09

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '21 Oct 2020'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 20:40:49

US3172469

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '16:29'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 20:40:49

US3172469

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User entered '21 Oct 2020 16:29'	System	21 Oct 2020 20:40:49

US3172469

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Left Arm (LEFT ARM)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 20:40:49

US3172469

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User entered 'ONCE'	System	21 Oct 2020 20:40:49

US3172469

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:32:09

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User entered 'INTRAMUSCULAR'	System	21 Oct 2020 20:40:49

US3172469

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:32:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:52:03

US3172469

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:32:09

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '21 Oct 2020'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:52:03

US3172469

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:32:09

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '16:06'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:52:03

US3172469

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User entered '21 Oct 2020 16:06'	System	22 Oct 2020 12:52:03

US3172469

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:32:09

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '21 Oct 2020'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:52:12

US3172469

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:32:09

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:52:12

US3172469

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:32:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:52:12

US3172469

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:32:09

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '16:10'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:52:12

US3172469

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User entered '21 Oct 2020 16:10'	System	22 Oct 2020 12:52:12

US3172469

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:32:09

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:52:12

US3172469

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:32:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:52:12

US3172469

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:32:09

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered empty.	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:52:12

US3172469

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User entered empty.	System	22 Oct 2020 12:52:12

US3172469

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Yes (Y)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	29 Oct 2020 17:47:32
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:52:16

US3172469

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:32:09

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User entered '1'	System	29 Oct 2020 17:47:32
User entered empty.	System	22 Oct 2020 12:52:16

US3172469

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
Data entry locked.	System	21 Oct 2020 20:40:49
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Oct 2020 20:40:49

US3172469

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:32:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-21T17:10:02', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'a254c405-ae48-4b78-bf48-a22a95b1a531'	System	21 Oct 2020 21:10:55
User entered 'Yes (Y)'	System	21 Oct 2020 21:10:55

US3172469

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:32:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-21T17:10:45', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'a254c405-ae48-4b78-bf48-a22a95b1a531'	System	21 Oct 2020 21:10:55
User entered '97.6'	System	21 Oct 2020 21:10:55

US3172469

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-21T17:10:50', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'a254c405-ae48-4b78-bf48-a22a95b1a531'	System	21 Oct 2020 21:10:55
User entered 'No (N)'	System	21 Oct 2020 21:10:55

US3172469

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:32:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-21T17:10:52', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'a254c405-ae48-4b78-bf48-a22a95b1a531'	System	21 Oct 2020 21:10:55
User entered '21 Oct 2020 17:10'	System	21 Oct 2020 21:10:55

US3172469

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:32:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '21 Oct 2020 16:49'	System	21 Oct 2020 20:40:49

US3172469

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:32:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '21 Oct 2020 19:19'	System	21 Oct 2020 20:40:49

US3172469

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
Data entry locked.	System	21 Oct 2020 20:40:49
User entered 'Day 1, after vaccination (at home)'	System	21 Oct 2020 20:40:49

US3172469

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:32:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-22T04:45:35', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '0e8b5479-0bf5-4208-a9d9-e6adbb75cd8a'	System	22 Oct 2020 08:46:23
User entered 'No (N)'	System	22 Oct 2020 08:46:23

US3172469

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-22T04:45:43', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '0e8b5479-0bf5-4208-a9d9-e6adbb75cd8a'	System	22 Oct 2020 08:46:23
User entered 'No (N)'	System	22 Oct 2020 08:46:23

US3172469

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:32:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-22T04:46:17', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '0e8b5479-0bf5-4208-a9d9-e6adbb75cd8a'	System	22 Oct 2020 08:46:23
User entered '22 Oct 2020 04:46'	System	22 Oct 2020 08:46:23

US3172469

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:32:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '21 Oct 2020 20:14'	System	21 Oct 2020 20:40:49

US3172469

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:32:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '22 Oct 2020 11:59'	System	21 Oct 2020 20:40:49

US3172469

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
Data entry locked.	System	21 Oct 2020 20:40:49
User entered 'Day 2'	System	21 Oct 2020 20:40:49

US3172469

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:32:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-22T13:02:55', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'ee46eff0-f19a-46d0-9d3f-bc4032048b2c'	System	22 Oct 2020 17:04:14
User entered 'Yes (Y)'	System	22 Oct 2020 17:04:14

US3172469

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:32:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-22T13:03:37', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'ee46eff0-f19a-46d0-9d3f-bc4032048b2c'	System	22 Oct 2020 17:04:14
User entered '98.0'	System	22 Oct 2020 17:04:14

US3172469

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-22T13:03:46', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'ee46eff0-f19a-46d0-9d3f-bc4032048b2c'	System	22 Oct 2020 17:04:14
User entered 'No (N)'	System	22 Oct 2020 17:04:14

US3172469

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:32:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-22T13:03:53', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'ee46eff0-f19a-46d0-9d3f-bc4032048b2c'	System	22 Oct 2020 17:04:14
User entered '22 Oct 2020 13:03'	System	22 Oct 2020 17:04:14

US3172469

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:32:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '22 Oct 2020 12:00'	System	21 Oct 2020 20:40:49

US3172469

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:32:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '23 Oct 2020 11:59'	System	21 Oct 2020 20:40:49

US3172469

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
Data entry locked.	System	21 Oct 2020 20:40:49
User entered 'Day 3'	System	21 Oct 2020 20:40:49

US3172469

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:32:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-23T12:01:38', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'ce0e8a74-c6b3-495f-8db0-80a91320fa8d'	System	23 Oct 2020 16:03:16
User entered 'Yes (Y)'	System	23 Oct 2020 16:03:16

US3172469

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:32:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-23T12:01:54', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'ce0e8a74-c6b3-495f-8db0-80a91320fa8d'	System	23 Oct 2020 16:03:16
User entered '98.0'	System	23 Oct 2020 16:03:16

US3172469

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-23T12:02:02', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'ce0e8a74-c6b3-495f-8db0-80a91320fa8d'	System	23 Oct 2020 16:03:16
User entered 'No (N)'	System	23 Oct 2020 16:03:16

US3172469

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:32:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-23T12:02:06', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'ce0e8a74-c6b3-495f-8db0-80a91320fa8d'	System	23 Oct 2020 16:03:16
User entered '23 Oct 2020 12:02'	System	23 Oct 2020 16:03:16

US3172469

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:32:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '23 Oct 2020 12:00'	System	21 Oct 2020 20:40:49

US3172469

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:32:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '24 Oct 2020 11:59'	System	21 Oct 2020 20:40:49

US3172469

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
Data entry locked.	System	21 Oct 2020 20:40:49
User entered 'Day 4'	System	21 Oct 2020 20:40:49

US3172469

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:32:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14

US3172469

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:32:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14

US3172469

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14

US3172469

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14

US3172469

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:32:09

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14

US3172469

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:32:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14

US3172469

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:32:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '24 Oct 2020 12:00'	System	21 Oct 2020 20:40:49

US3172469

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:32:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '25 Oct 2020 11:59'	System	21 Oct 2020 20:40:49

US3172469

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
Data entry locked.	System	21 Oct 2020 20:40:49
User entered 'Day 5'	System	21 Oct 2020 20:40:49

US3172469

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:32:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-26T10:48:30', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'abedc7c8-279c-4670-8f77-e0ed44b43f48'	System	26 Oct 2020 14:48:58
User entered 'Yes (Y)'	System	26 Oct 2020 14:48:58

US3172469

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:32:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-26T10:48:44', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'abedc7c8-279c-4670-8f77-e0ed44b43f48'	System	26 Oct 2020 14:48:58
User entered '98.0'	System	26 Oct 2020 14:48:58

US3172469

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-26T10:48:51', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'abedc7c8-279c-4670-8f77-e0ed44b43f48'	System	26 Oct 2020 14:48:58
User entered 'No (N)'	System	26 Oct 2020 14:48:58

US3172469

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:32:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-26T10:48:56', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'abedc7c8-279c-4670-8f77-e0ed44b43f48'	System	26 Oct 2020 14:48:58
User entered '26 Oct 2020 10:48'	System	26 Oct 2020 14:48:58

US3172469

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:32:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '25 Oct 2020 12:00'	System	21 Oct 2020 20:40:49

US3172469

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:32:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '26 Oct 2020 11:59'	System	21 Oct 2020 20:40:49

US3172469

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
Data entry locked.	System	21 Oct 2020 20:40:49
User entered 'Day 6'	System	21 Oct 2020 20:40:49

US3172469

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:32:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-27T09:47:05', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '5338e5bb-570a-4fd8-923d-dd254425a9f5'	System	27 Oct 2020 13:48:04
User entered 'Yes (Y)'	System	27 Oct 2020 13:48:04

US3172469

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:32:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-27T09:47:50', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '5338e5bb-570a-4fd8-923d-dd254425a9f5'	System	27 Oct 2020 13:48:04
User entered '98.8'	System	27 Oct 2020 13:48:04

US3172469

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-27T09:47:57', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '5338e5bb-570a-4fd8-923d-dd254425a9f5'	System	27 Oct 2020 13:48:04
User entered 'No (N)'	System	27 Oct 2020 13:48:04

US3172469

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:32:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-27T09:48:02', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '5338e5bb-570a-4fd8-923d-dd254425a9f5'	System	27 Oct 2020 13:48:04
User entered '27 Oct 2020 09:48'	System	27 Oct 2020 13:48:04

US3172469

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:32:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '26 Oct 2020 12:00'	System	21 Oct 2020 20:40:49

US3172469

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:32:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '27 Oct 2020 11:59'	System	21 Oct 2020 20:40:49

US3172469

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
Data entry locked.	System	21 Oct 2020 20:40:49
User entered 'Day 7'	System	21 Oct 2020 20:40:49

US3172469

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:32:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-27T14:55:33', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '8dd46747-8ac5-4a29-8027-2add8e024bed'	System	27 Oct 2020 18:56:11
User entered 'Yes (Y)'	System	27 Oct 2020 18:56:11

US3172469

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:32:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-27T14:55:50', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '8dd46747-8ac5-4a29-8027-2add8e024bed'	System	27 Oct 2020 18:56:11
User entered '98.0'	System	27 Oct 2020 18:56:11

US3172469

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-27T14:55:57', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '8dd46747-8ac5-4a29-8027-2add8e024bed'	System	27 Oct 2020 18:56:11
User entered 'No (N)'	System	27 Oct 2020 18:56:11

US3172469

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:32:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-27T14:56:10', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '8dd46747-8ac5-4a29-8027-2add8e024bed'	System	27 Oct 2020 18:56:11
User entered '27 Oct 2020 14:56'	System	27 Oct 2020 18:56:11

US3172469

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:32:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '27 Oct 2020 12:00'	System	21 Oct 2020 20:40:49

US3172469

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:32:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '28 Oct 2020 11:59'	System	21 Oct 2020 20:40:49

US3172469

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
Data entry locked.	System	21 Oct 2020 20:40:49
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Oct 2020 20:40:49

US3172469

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:32:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-21T17:10:59', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '8e3b3acc-4048-412d-b03e-201dcaed5b28'	System	21 Oct 2020 21:11:15
User entered 'None (1)'	System	21 Oct 2020 21:11:15

US3172469

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-21T17:11:06', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '8e3b3acc-4048-412d-b03e-201dcaed5b28'	System	21 Oct 2020 21:11:15
User entered 'No (N)'	System	21 Oct 2020 21:11:15

US3172469

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-21T17:11:08', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '8e3b3acc-4048-412d-b03e-201dcaed5b28'	System	21 Oct 2020 21:11:15
User entered 'No (N)'	System	21 Oct 2020 21:11:15

US3172469

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:32:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-21T17:11:12', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '8e3b3acc-4048-412d-b03e-201dcaed5b28'	System	21 Oct 2020 21:11:15
User entered 'None (1)'	System	21 Oct 2020 21:11:15

US3172469

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:32:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-21T17:11:13', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '8e3b3acc-4048-412d-b03e-201dcaed5b28'	System	21 Oct 2020 21:11:15
User entered '21 Oct 2020 17:11'	System	21 Oct 2020 21:11:15

US3172469

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:32:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '21 Oct 2020 16:49'	System	21 Oct 2020 20:40:49

US3172469

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:32:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '21 Oct 2020 19:19'	System	21 Oct 2020 20:40:49

US3172469

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
Data entry locked.	System	21 Oct 2020 20:40:49
User entered 'Day 1, after vaccination (at home)'	System	21 Oct 2020 20:40:49

US3172469

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:32:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-22T04:47:14', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '5cfbdb2e-b451-4da0-9404-771f879d4872'	System	22 Oct 2020 08:47:59
User entered 'Any use of prescription pain reliever or System prevents daily activity (4)'		22 Oct 2020 08:47:59

US3172469

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-22T04:47:29', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '5cfbdb2e-b451-4da0-9404-771f879d4872'	System	22 Oct 2020 08:47:59
User entered 'No (N)'	System	22 Oct 2020 08:47:59

US3172469

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-22T04:47:33', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '5cfbdb2e-b451-4da0-9404-771f879d4872'	System	22 Oct 2020 08:47:59
User entered 'No (N)'	System	22 Oct 2020 08:47:59

US3172469

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:32:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-22T04:47:39', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '5cfbdb2e-b451-4da0-9404-771f879d4872'	System	22 Oct 2020 08:47:59
User entered 'None (1)'	System	22 Oct 2020 08:47:59

US3172469

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:32:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-22T04:47:57', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '5cfbdb2e-b451-4da0-9404-771f879d4872'	System	22 Oct 2020 08:47:59
User entered '22 Oct 2020 04:47'	System	22 Oct 2020 08:47:59

US3172469

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:32:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '21 Oct 2020 20:14'	System	21 Oct 2020 20:40:49

US3172469

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:32:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '22 Oct 2020 11:59'	System	21 Oct 2020 20:40:49

US3172469

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
Data entry locked.	System	21 Oct 2020 20:40:49
User entered 'Day 2'	System	21 Oct 2020 20:40:49

US3172469

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:32:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-23T08:27:22', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'cf7322ff-cb73-42e4-98dc-c849c9609b13'	System	23 Oct 2020 12:27:37
User entered 'Does not interfere with activity (2)'	System	23 Oct 2020 12:27:37

US3172469

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-23T08:26:22', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'cf7322ff-cb73-42e4-98dc-c849c9609b13'	System	23 Oct 2020 12:27:37
User entered 'No (N)'	System	23 Oct 2020 12:27:37

US3172469

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-23T08:26:27', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'cf7322ff-cb73-42e4-98dc-c849c9609b13'	System	23 Oct 2020 12:27:37
User entered 'No (N)'	System	23 Oct 2020 12:27:37

US3172469

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:32:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-23T08:26:33', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'cf7322ff-cb73-42e4-98dc-c849c9609b13'	System	23 Oct 2020 12:27:37
User entered 'None (1)'	System	23 Oct 2020 12:27:37

US3172469

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:32:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-23T08:27:34', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'cf7322ff-cb73-42e4-98dc-c849c9609b13'	System	23 Oct 2020 12:27:37
User entered '23 Oct 2020 08:27'	System	23 Oct 2020 12:27:37

US3172469

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:32:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '22 Oct 2020 12:00'	System	21 Oct 2020 20:40:49

US3172469

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:32:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '23 Oct 2020 11:59'	System	21 Oct 2020 20:40:49

US3172469

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
Data entry locked.	System	21 Oct 2020 20:40:49
User entered 'Day 3'	System	21 Oct 2020 20:40:49

US3172469

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:32:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-23T12:02:49', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '8ab8c67b-07af-40be-9cd3-a2abc81d2290'	System	23 Oct 2020 16:04:49
User entered 'Any use of prescription pain reliever or System prevents daily activity (4)'		23 Oct 2020 16:04:49

US3172469

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-23T12:02:25', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '8ab8c67b-07af-40be-9cd3-a2abc81d2290'	System	23 Oct 2020 16:04:49
User entered 'No (N)'	System	23 Oct 2020 16:04:49

US3172469

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-23T12:02:29', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '8ab8c67b-07af-40be-9cd3-a2abc81d2290'	System	23 Oct 2020 16:04:49
User entered 'No (N)'	System	23 Oct 2020 16:04:49

US3172469

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:32:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-23T12:02:33', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '8ab8c67b-07af-40be-9cd3-a2abc81d2290'	System	23 Oct 2020 16:04:49
User entered 'None (1)'	System	23 Oct 2020 16:04:49

US3172469

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:32:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-23T12:02:54', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '8ab8c67b-07af-40be-9cd3-a2abc81d2290'	System	23 Oct 2020 16:04:49
User entered '23 Oct 2020 12:02'	System	23 Oct 2020 16:04:49

US3172469

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:32:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '23 Oct 2020 12:00'	System	21 Oct 2020 20:40:49

US3172469

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:32:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '24 Oct 2020 11:59'	System	21 Oct 2020 20:40:49

US3172469

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
Data entry locked.	System	21 Oct 2020 20:40:49
User entered 'Day 4'	System	21 Oct 2020 20:40:49

US3172469

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:32:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14

US3172469

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14

US3172469

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:32:09

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14

US3172469

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14

US3172469

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:32:09

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14

US3172469

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:32:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14

US3172469

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:32:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14

US3172469

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:32:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '24 Oct 2020 12:00'	System	21 Oct 2020 20:40:49

US3172469

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:32:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '25 Oct 2020 11:59'	System	21 Oct 2020 20:40:49

US3172469

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
Data entry locked.	System	21 Oct 2020 20:40:49
User entered 'Day 5'	System	21 Oct 2020 20:40:49

US3172469

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:32:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-26T10:49:23', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'd7a6a553-ee42-492e-b6c9-5d993a2fcbd0'	System	26 Oct 2020 14:50:03
User entered 'Any use of prescription pain reliever or System prevents daily activity (4)'		26 Oct 2020 14:50:03

US3172469

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-26T10:49:28', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'd7a6a553-ee42-492e-b6c9-5d993a2fcbd0'	System	26 Oct 2020 14:50:03
User entered 'No (N)'	System	26 Oct 2020 14:50:03

US3172469

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-26T10:49:33', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'd7a6a553-ee42-492e-b6c9-5d993a2fcbd0'	System	26 Oct 2020 14:50:03
User entered 'No (N)'	System	26 Oct 2020 14:50:03

US3172469

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:32:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-26T10:49:50', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'd7a6a553-ee42-492e-b6c9-5d993a2fcbd0'	System	26 Oct 2020 14:50:03
User entered 'Any use of prescription pain reliever or System prevents daily activity (4)'		26 Oct 2020 14:50:03

US3172469

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:32:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-26T10:50:01', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'd7a6a553-ee42-492e-b6c9-5d993a2fcbd0' User entered '26 Oct 2020 10:50'	System	26 Oct 2020 14:50:03
	System	26 Oct 2020 14:50:03

US3172469

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:32:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '25 Oct 2020 12:00'	System	21 Oct 2020 20:40:49

US3172469

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:32:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '26 Oct 2020 11:59'	System	21 Oct 2020 20:40:49

US3172469

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
Data entry locked.	System	21 Oct 2020 20:40:49
User entered 'Day 6'	System	21 Oct 2020 20:40:49

US3172469

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:32:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-27T09:48:17', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '911266e5-fe6f-4489-98cf-22207730c17f'	System	27 Oct 2020 13:48:44
User entered 'None (1)'	System	27 Oct 2020 13:48:44

US3172469

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-27T09:48:24', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '911266e5-fe6f-4489-98cf-22207730c17f'	System	27 Oct 2020 13:48:44
User entered 'No (N)'	System	27 Oct 2020 13:48:44

US3172469

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-27T09:48:28', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '911266e5-fe6f-4489-98cf-22207730c17f'	System	27 Oct 2020 13:48:44
User entered 'No (N)'	System	27 Oct 2020 13:48:44

US3172469

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:32:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-27T09:48:33', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '911266e5-fe6f-4489-98cf-22207730c17f'	System	27 Oct 2020 13:48:44
User entered 'None (1)'	System	27 Oct 2020 13:48:44

US3172469

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:32:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-27T09:48:42', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '911266e5-fe6f-4489-98cf-22207730c17f' User entered '27 Oct 2020 09:48'	System	27 Oct 2020 13:48:44
	System	27 Oct 2020 13:48:44

US3172469

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:32:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '26 Oct 2020 12:00'	System	21 Oct 2020 20:40:49

US3172469

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:32:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '27 Oct 2020 11:59'	System	21 Oct 2020 20:40:49

US3172469

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
Data entry locked.	System	21 Oct 2020 20:40:49
User entered 'Day 7'	System	21 Oct 2020 20:40:49

US3172469

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:32:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-27T14:56:16', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'a30d4cb7-3e67-4da2-be29-d3f40ab90336'	System	27 Oct 2020 18:56:40
User entered 'None (1)'	System	27 Oct 2020 18:56:40

US3172469

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-27T14:56:23', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'a30d4cb7-3e67-4da2-be29-d3f40ab90336'	System	27 Oct 2020 18:56:40
User entered 'No (N)'	System	27 Oct 2020 18:56:40

US3172469

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-27T14:56:26', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'a30d4cb7-3e67-4da2-be29-d3f40ab90336'	System	27 Oct 2020 18:56:40
User entered 'No (N)'	System	27 Oct 2020 18:56:40

US3172469

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:32:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-27T14:56:32', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'a30d4cb7-3e67-4da2-be29-d3f40ab90336'	System	27 Oct 2020 18:56:40
User entered 'None (1)'	System	27 Oct 2020 18:56:40

US3172469

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:32:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-27T14:56:39', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'a30d4cb7-3e67-4da2-be29-d3f40ab90336'	System	27 Oct 2020 18:56:40
User entered '27 Oct 2020 14:56'	System	27 Oct 2020 18:56:40

US3172469

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:32:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '27 Oct 2020 12:00'	System	21 Oct 2020 20:40:49

US3172469

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:32:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '28 Oct 2020 11:59'	System	21 Oct 2020 20:40:49

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
Data entry locked.	System	21 Oct 2020 20:40:49
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Oct 2020 20:40:49

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:32:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-21T17:11:17', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '81b59ada-83cc-4fbd-b60a-a6e39f3a47a8'	System	21 Oct 2020 21:11:37
User entered 'None (0)'	System	21 Oct 2020 21:11:37

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:32:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-21T17:11:19', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '81b59ada-83cc-4fbd-b60a-a6e39f3a47a8'	System	21 Oct 2020 21:11:37
User entered 'None (0)'	System	21 Oct 2020 21:11:37

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:32:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-21T17:11:21', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '81b59ada-83cc-4fbd-b60a-a6e39f3a47a8'	System	21 Oct 2020 21:11:37
User entered 'None (0)'	System	21 Oct 2020 21:11:37

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:32:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-21T17:11:25', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '81b59ada-83cc-4fbd-b60a-a6e39f3a47a8'	System	21 Oct 2020 21:11:37
User entered 'None (0)'	System	21 Oct 2020 21:11:37

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:32:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-21T17:11:27', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '81b59ada-83cc-4fbd-b60a-a6e39f3a47a8'	System	21 Oct 2020 21:11:37
User entered 'None (0)'	System	21 Oct 2020 21:11:37

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:32:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-21T17:11:29', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '81b59ada-83cc-4fbd-b60a-a6e39f3a47a8'	System	21 Oct 2020 21:11:37
User entered 'None (0)'	System	21 Oct 2020 21:11:37

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-21T17:11:34', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '81b59ada-83cc-4fbd-b60a-a6e39f3a47a8'	System	21 Oct 2020 21:11:37
User entered 'No (N)'	System	21 Oct 2020 21:11:37

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:32:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-21T17:11:35', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '81b59ada-83cc-4fbd-b60a-a6e39f3a47a8'	System	21 Oct 2020 21:11:37
User entered '21 Oct 2020 17:11'	System	21 Oct 2020 21:11:37

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:32:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '21 Oct 2020 16:49'	System	21 Oct 2020 20:40:49

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:32:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '21 Oct 2020 19:19'	System	21 Oct 2020 20:40:49

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
Data entry locked.	System	21 Oct 2020 20:40:49
User entered 'Day 1, after vaccination (at home)'	System	21 Oct 2020 20:40:49

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:32:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-22T04:48:27', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'b580cadf-1668-49e2-9140-8f2db441b17c'	System	22 Oct 2020 08:48:59
User entered 'Any use of prescription pain reliever or System prevents daily activity (3)'		22 Oct 2020 08:48:59

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:32:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-22T04:48:38', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'b580cadf-1668-49e2-9140-8f2db441b17c'	System	22 Oct 2020 08:48:59
User entered 'None (0)'	System	22 Oct 2020 08:48:59

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:32:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-22T04:48:42', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'b580cadf-1668-49e2-9140-8f2db441b17c'	System	22 Oct 2020 08:48:59
User entered 'None (0)'	System	22 Oct 2020 08:48:59

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:32:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-22T04:48:44', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'b580cadf-1668-49e2-9140-8f2db441b17c'	System	22 Oct 2020 08:48:59
User entered 'None (0)'	System	22 Oct 2020 08:48:59

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:32:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-22T04:48:48', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'b580cadf-1668-49e2-9140-8f2db441b17c'	System	22 Oct 2020 08:48:59
User entered 'None (0)'	System	22 Oct 2020 08:48:59

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:32:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-22T04:48:50', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'b580cadf-1668-49e2-9140-8f2db441b17c'	System	22 Oct 2020 08:48:59
User entered 'None (0)'	System	22 Oct 2020 08:48:59

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-22T04:48:53', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'b580cadf-1668-49e2-9140-8f2db441b17c'	System	22 Oct 2020 08:48:59
User entered 'No (N)'	System	22 Oct 2020 08:48:59

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:32:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-22T04:48:56', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'b580cadf-1668-49e2-9140-8f2db441b17c'	System	22 Oct 2020 08:48:59
User entered '22 Oct 2020 04:48'	System	22 Oct 2020 08:48:59

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:32:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '21 Oct 2020 20:14'	System	21 Oct 2020 20:40:49

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:32:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '22 Oct 2020 11:59'	System	21 Oct 2020 20:40:49

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
Data entry locked.	System	21 Oct 2020 20:40:49
User entered 'Day 2'	System	21 Oct 2020 20:40:49

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:32:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-23T08:27:55', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '3c874f47-d17c-473d-b593-1763fa56f0cf'	System	23 Oct 2020 12:28:52
User entered 'Any use of prescription pain reliever or System prevents daily activity (3)'		23 Oct 2020 12:28:52

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:32:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-23T08:28:09', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '3c874f47-d17c-473d-b593-1763fa56f0cf'	System	23 Oct 2020 12:28:52
User entered 'None (0)'	System	23 Oct 2020 12:28:52

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:32:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-23T08:28:24', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '3c874f47-d17c-473d-b593-1763fa56f0cf'	System	23 Oct 2020 12:28:52
User entered 'None (0)'	System	23 Oct 2020 12:28:52

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:32:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-23T08:28:30', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '3c874f47-d17c-473d-b593-1763fa56f0cf'	System	23 Oct 2020 12:28:52
User entered 'None (0)'	System	23 Oct 2020 12:28:52

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:32:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-23T08:28:34', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '3c874f47-d17c-473d-b593-1763fa56f0cf'	System	23 Oct 2020 12:28:52
User entered 'None (0)'	System	23 Oct 2020 12:28:52

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:32:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-23T08:28:36', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '3c874f47-d17c-473d-b593-1763fa56f0cf'	System	23 Oct 2020 12:28:52
User entered 'None (0)'	System	23 Oct 2020 12:28:52

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-23T08:28:41', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '3c874f47-d17c-473d-b593-1763fa56f0cf'	System	23 Oct 2020 12:28:52
User entered 'No (N)'	System	23 Oct 2020 12:28:52

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:32:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-23T08:28:49', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '3c874f47-d17c-473d-b593-1763fa56f0cf' User entered '23 Oct 2020 08:28'	System	23 Oct 2020 12:28:52
	System	23 Oct 2020 12:28:52

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:32:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '22 Oct 2020 12:00'	System	21 Oct 2020 20:40:49

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:32:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '23 Oct 2020 11:59'	System	21 Oct 2020 20:40:49

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
Data entry locked.	System	21 Oct 2020 20:40:49
User entered 'Day 3'	System	21 Oct 2020 20:40:49

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:32:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-23T12:03:10', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'a513a17e-6ac0-4510-afe9-6d50e5b8b64c'	System	23 Oct 2020 16:05:56
User entered 'Any use of prescription pain reliever or System prevents daily activity (3)'		23 Oct 2020 16:05:56

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:32:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-23T12:03:21', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'a513a17e-6ac0-4510-afe9-6d50e5b8b64c'	System	23 Oct 2020 16:05:56
User entered 'Significant; prevents daily activity (3)'	System	23 Oct 2020 16:05:56

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:32:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-23T12:03:28', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'a513a17e-6ac0-4510-afe9-6d50e5b8b64c'	System	23 Oct 2020 16:05:56
User entered 'None (0)'	System	23 Oct 2020 16:05:56

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:32:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-23T12:03:31', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'a513a17e-6ac0-4510-afe9-6d50e5b8b64c'	System	23 Oct 2020 16:05:56
User entered 'None (0)'	System	23 Oct 2020 16:05:56

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:32:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-23T12:03:34', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'a513a17e-6ac0-4510-afe9-6d50e5b8b64c'	System	23 Oct 2020 16:05:56
User entered 'None (0)'	System	23 Oct 2020 16:05:56

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:32:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-23T12:03:37', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'a513a17e-6ac0-4510-afe9-6d50e5b8b64c'	System	23 Oct 2020 16:05:56
User entered 'None (0)'	System	23 Oct 2020 16:05:56

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-23T12:03:40', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'a513a17e-6ac0-4510-afe9-6d50e5b8b64c'	System	23 Oct 2020 16:05:56
User entered 'No (N)'	System	23 Oct 2020 16:05:56

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:32:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-23T12:03:44', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'a513a17e-6ac0-4510-afe9-6d50e5b8b64c'	System	23 Oct 2020 16:05:56
User entered '23 Oct 2020 12:03'	System	23 Oct 2020 16:05:56

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:32:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '23 Oct 2020 12:00'	System	21 Oct 2020 20:40:49

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:32:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '24 Oct 2020 11:59'	System	21 Oct 2020 20:40:49

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
Data entry locked.	System	21 Oct 2020 20:40:49
User entered 'Day 4'	System	21 Oct 2020 20:40:49

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:32:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:32:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:32:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:32:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:32:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:32:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:32:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:32:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '24 Oct 2020 12:00'	System	21 Oct 2020 20:40:49

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:32:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '25 Oct 2020 11:59'	System	21 Oct 2020 20:40:49

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
Data entry locked.	System	21 Oct 2020 20:40:49
User entered 'Day 5'	System	21 Oct 2020 20:40:49

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:32:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-26T10:50:12', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '5c650b5e-6f0a-4986-813f-078d34dfacce'	System	26 Oct 2020 14:50:45
User entered 'None (0)'	System	26 Oct 2020 14:50:45

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:32:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-26T10:50:19', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '5c650b5e-6f0a-4986-813f-078d34dfacce'	System	26 Oct 2020 14:50:45
User entered 'None (0)'	System	26 Oct 2020 14:50:45

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:32:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-26T10:50:22', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '5c650b5e-6f0a-4986-813f-078d34dfacce'	System	26 Oct 2020 14:50:45
User entered 'None (0)'	System	26 Oct 2020 14:50:45

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:32:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-26T10:50:25', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '5c650b5e-6f0a-4986-813f-078d34dfacce'	System	26 Oct 2020 14:50:45
User entered 'None (0)'	System	26 Oct 2020 14:50:45

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:32:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-26T10:50:27', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '5c650b5e-6f0a-4986-813f-078d34dfacce'	System	26 Oct 2020 14:50:45
User entered 'None (0)'	System	26 Oct 2020 14:50:45

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:32:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-26T10:50:30', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '5c650b5e-6f0a-4986-813f-078d34dfacce'	System	26 Oct 2020 14:50:45
User entered 'None (0)'	System	26 Oct 2020 14:50:45

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-26T10:50:33', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '5c650b5e-6f0a-4986-813f-078d34dfacce'	System	26 Oct 2020 14:50:45
User entered 'No (N)'	System	26 Oct 2020 14:50:45

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:32:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-26T10:50:42', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '5c650b5e-6f0a-4986-813f-078d34dfacce' User entered '26 Oct 2020 10:50'	System	26 Oct 2020 14:50:45
	System	26 Oct 2020 14:50:45

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:32:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '25 Oct 2020 12:00'	System	21 Oct 2020 20:40:49

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:32:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '26 Oct 2020 11:59'	System	21 Oct 2020 20:40:49

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
Data entry locked.	System	21 Oct 2020 20:40:49
User entered 'Day 6'	System	21 Oct 2020 20:40:49

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:32:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-27T09:48:52', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '0354b8cc-1a64-4f82-8f2b-1bd87853ddc5'	System	27 Oct 2020 13:49:20
User entered 'None (0)'	System	27 Oct 2020 13:49:20

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:32:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-27T09:48:55', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '0354b8cc-1a64-4f82-8f2b-1bd87853ddc5'	System	27 Oct 2020 13:49:20
User entered 'None (0)'	System	27 Oct 2020 13:49:20

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:32:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-27T09:48:58', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '0354b8cc-1a64-4f82-8f2b-1bd87853ddc5'	System	27 Oct 2020 13:49:20
User entered 'None (0)'	System	27 Oct 2020 13:49:20

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:32:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-27T09:49:01', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '0354b8cc-1a64-4f82-8f2b-1bd87853ddc5'	System	27 Oct 2020 13:49:20
User entered 'None (0)'	System	27 Oct 2020 13:49:20

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:32:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-27T09:49:04', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '0354b8cc-1a64-4f82-8f2b-1bd87853ddc5'	System	27 Oct 2020 13:49:20
User entered 'None (0)'	System	27 Oct 2020 13:49:20

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:32:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-27T09:49:07', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '0354b8cc-1a64-4f82-8f2b-1bd87853ddc5'	System	27 Oct 2020 13:49:20
User entered 'None (0)'	System	27 Oct 2020 13:49:20

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-27T09:49:12', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '0354b8cc-1a64-4f82-8f2b-1bd87853ddc5'	System	27 Oct 2020 13:49:20
User entered 'No (N)'	System	27 Oct 2020 13:49:20

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:32:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-10-27T09:49:16', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '0354b8cc-1a64-4f82-8f2b-1bd87853ddc5'	System	27 Oct 2020 13:49:20
User entered '27 Oct 2020 09:49'	System	27 Oct 2020 13:49:20

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:32:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '26 Oct 2020 12:00'	System	21 Oct 2020 20:40:49

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:32:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '27 Oct 2020 11:59'	System	21 Oct 2020 20:40:49

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
Data entry locked.	System	21 Oct 2020 20:40:49
User entered 'Day 7'	System	21 Oct 2020 20:40:49

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:32:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:32:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:32:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:32:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:32:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:32:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:32:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:32:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '27 Oct 2020 12:00'	System	21 Oct 2020 20:40:49

US3172469

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:32:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '28 Oct 2020 11:59'	System	21 Oct 2020 20:40:49

US3172469

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:09

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	29 Oct 2020 18:24:25

US3172469

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '28 Oct 2020'	Mariete Rendon (b) (4) (b) (4)	29 Oct 2020 18:24:25

US3172469

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:09

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Contact Made (CONTACT MADE)'	Mariete Rendon (b) (4) (b) (4)	29 Oct 2020 18:24:25

US3172469

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:09

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered empty.	Mariete Rendon (b) (4) (b) (4)	29 Oct 2020 18:24:25

US3172469

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	05 Nov 2020 22:57:43
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	29 Oct 2020 18:30:40

US3172469

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:09

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User entered '1'	System	05 Nov 2020 22:57:43
User entered empty.	System	29 Oct 2020 18:30:40

US3172469

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:09

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	05 Nov 2020 22:58:08

US3172469

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '05 Nov 2020'	Jessie Downs (b) (4) (b) (4)	05 Nov 2020 22:58:08

US3172469

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:09

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	05 Nov 2020 22:58:08

US3172469

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:09

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Nov 2020 22:58:08

US3172469

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	05 Nov 2020 22:57:48

US3172469

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:09

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User entered '1'	System	05 Nov 2020 22:57:48

US3172469

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:09

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:15:26

US3172469

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '13 Nov 2020'	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:15:26

US3172469

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:09

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Contact Not Made (CONTACT NOT MADE)'	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:15:26

US3172469

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:09

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User closed query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided. Please review and reconcile.' (Site from System).	System	18 Nov 2020 16:21:12
User entered 'NO VOICEMAIL SET UP. CONTACTED SUBJECT EMERGENCY CONTACT TO CONTACT THE SITE.' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:21:12
User opened query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided. Please review and reconcile.' (Site from System).	System	18 Nov 2020 16:15:26
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:15:26

US3172469

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:15:47

US3172469

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:09

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User entered '1'	System	18 Nov 2020 16:15:47

US3172469

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:32:09

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:18:08

US3172469

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '18 Nov 2020'	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:18:08

US3172469

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Clinic (Clinic)'	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:18:08

US3172469

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:32:09

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User entered 'VISIT2'	System	18 Nov 2020 16:18:08

US3172469

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:09

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User accepted default value 'Pre-Dose (PREDOSE)'	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:19:54

US3172469

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:09

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:19:54

US3172469

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '18 Nov 2020'	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:19:54

US3172469

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '09:22'	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:19:54

US3172469

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User entered '18 Nov 2020 09:22'	System	18 Nov 2020 16:19:54

US3172469

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:09

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '36.7' C	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:19:54

US3172469

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:09

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Oral (Oral)'	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:19:54

US3172469

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:09

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:19:54

US3172469

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:09

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '59'	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:19:54

US3172469

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:09

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User entered 'bpm'	System	18 Nov 2020 16:19:54

US3172469

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '16'	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:19:54

US3172469

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User entered 'breaths/min'	System	18 Nov 2020 16:19:54

US3172469

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:09

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '131'	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:19:54

US3172469

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User entered 'mmHg'	System	18 Nov 2020 16:19:54

US3172469

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:09

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '79'	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:19:54

US3172469

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:32:09

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User entered 'mmHg'	System	18 Nov 2020 16:19:54

US3172469

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:09

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User accepted default value 'Post-Dose (POSTDOSE)'	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:19:54

US3172469

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:53:46
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:19:54

US3172469

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '18 Nov 2020' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:53:46
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:19:54

US3172469

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '11:34' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:53:46
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:19:54

US3172469

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User entered '18 Nov 2020 11:34'	System	18 Nov 2020 16:53:46
User entered empty.	System	18 Nov 2020 16:19:54

US3172469

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:09

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '36.5' C reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:53:46
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:19:54

US3172469

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:09

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Oral (Oral)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:53:46
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:19:54

US3172469

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:09

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:19:54

US3172469

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:09

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '61' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:53:46
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:19:54

US3172469

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:09

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User entered 'bpm'	System	18 Nov 2020 16:53:46
User entered empty.	System	18 Nov 2020 16:19:54

US3172469

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '14' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:53:46
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:19:54

US3172469

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User entered 'breaths/min'	System	18 Nov 2020 16:53:46
User entered empty.	System	18 Nov 2020 16:19:54

US3172469

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:09

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '135' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:53:46
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:19:54

US3172469

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User entered 'mmHg'	System	18 Nov 2020 16:53:46
User entered empty.	System	18 Nov 2020 16:19:54

US3172469

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:09

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '83' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:53:46
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:19:54

US3172469

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:32:09

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User entered 'mmHg'	System	18 Nov 2020 16:53:46
User entered empty.	System	18 Nov 2020 16:19:54

US3172469

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:32:09

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:19:03

US3172469

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:32:09

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '18 Nov 2020'	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:19:03

US3172469

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:32:09

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:16:30

US3172469

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:32:09

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:16:30

US3172469

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:32:09

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)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:16:30

US3172469

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:32:09

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User entered 'MRNA-1273 OR PLACEBO'	System	18 Nov 2020 16:16:30

US3172469

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:32:09

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '18 Nov 2020'	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:16:30

US3172469

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '11:04'	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:16:30

US3172469

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User entered '18 Nov 2020 11:04'	System	18 Nov 2020 16:16:30

US3172469

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:32:09

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Left Arm (LEFT ARM)'	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:16:30

US3172469

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User entered 'ONCE'	System	18 Nov 2020 16:16:30

US3172469

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:32:09

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User entered 'INTRAMUSCULAR'	System	18 Nov 2020 16:16:30

US3172469

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:32:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:18:28

US3172469

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:32:09

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '18 Nov 2020'	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:18:28

US3172469

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:32:09

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '10:47'	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:18:28

US3172469

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User entered '18 Nov 2020 10:47'	System	18 Nov 2020 16:18:28

US3172469

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:32:09

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '18 Nov 2020'	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:18:45

US3172469

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:32:09

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:18:45

US3172469

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:32:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:18:45

US3172469

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:32:09

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '10:49'	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:18:45

US3172469

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User entered '18 Nov 2020 10:49'	System	18 Nov 2020 16:18:45

US3172469

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:32:09

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:18:45

US3172469

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:32:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:18:45

US3172469

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:32:09

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:18:45

US3172469

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User entered empty.	System	18 Nov 2020 16:18:45

US3172469

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:18:50

US3172469

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:09

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User entered '1'	System	18 Nov 2020 16:18:50

US3172469

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
Data entry locked.	System	18 Nov 2020 16:16:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Nov 2020 16:16:30

US3172469

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:32:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-18T11:41:12', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'edcc838e-62d2-4248-b9b2-30437215ac40'	System	18 Nov 2020 16:41:38
User entered 'Yes (Y)'	System	18 Nov 2020 16:41:38

US3172469

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:32:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-18T11:41:25', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'edcc838e-62d2-4248-b9b2-30437215ac40'	System	18 Nov 2020 16:41:38
User entered '97.7'	System	18 Nov 2020 16:41:38

US3172469

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-18T11:41:29', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'edcc838e-62d2-4248-b9b2-30437215ac40'	System	18 Nov 2020 16:41:38
User entered 'No (N)'	System	18 Nov 2020 16:41:38

US3172469

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:32:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-18T11:41:33', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'edcc838e-62d2-4248-b9b2-30437215ac40'	System	18 Nov 2020 16:41:38
User entered '18 Nov 2020 11:41'	System	18 Nov 2020 16:41:38

US3172469

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:32:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '18 Nov 2020 11:24'	System	18 Nov 2020 16:16:30

US3172469

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:32:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '18 Nov 2020 13:54'	System	18 Nov 2020 16:16:30

US3172469

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
Data entry locked.	System	18 Nov 2020 16:16:30
User entered 'Day 1, after vaccination (at home)'	System	18 Nov 2020 16:16:30

US3172469

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:32:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-18T18:01:22', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '59b75895-27d6-43c6-9bcc-558988bac758'	System	18 Nov 2020 23:02:16
User entered 'Yes (Y)'	System	18 Nov 2020 23:02:16

US3172469

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:32:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-18T18:01:56', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '59b75895-27d6-43c6-9bcc-558988bac758'	System	18 Nov 2020 23:02:16
User entered '98.5'	System	18 Nov 2020 23:02:16

US3172469

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-18T18:02:10', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '59b75895-27d6-43c6-9bcc-558988bac758'	System	18 Nov 2020 23:02:16
User entered 'No (N)'	System	18 Nov 2020 23:02:16

US3172469

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:32:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-18T18:02:13', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '59b75895-27d6-43c6-9bcc-558988bac758'	System	18 Nov 2020 23:02:16
User entered '18 Nov 2020 18:02'	System	18 Nov 2020 23:02:16

US3172469

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:32:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '18 Nov 2020 14:49'	System	18 Nov 2020 16:16:30

US3172469

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:32:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '19 Nov 2020 11:59'	System	18 Nov 2020 16:16:30

US3172469

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
Data entry locked.	System	18 Nov 2020 16:16:30
User entered 'Day 2'	System	18 Nov 2020 16:16:30

US3172469

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:32:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-19T17:23:44', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '4a51eff5-5de5-445c-9770-69e85617f910'	System	19 Nov 2020 22:24:14
User entered 'Yes (Y)'	System	19 Nov 2020 22:24:14

US3172469

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:32:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-19T17:24:00', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '4a51eff5-5de5-445c-9770-69e85617f910'	System	19 Nov 2020 22:24:14
User entered '95.3'	System	19 Nov 2020 22:24:14

US3172469

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-19T17:24:07', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '4a51eff5-5de5-445c-9770-69e85617f910'	System	19 Nov 2020 22:24:14
User entered 'No (N)'	System	19 Nov 2020 22:24:14

US3172469

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:32:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-19T17:24:10', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '4a51eff5-5de5-445c-9770-69e85617f910'	System	19 Nov 2020 22:24:14
User entered '19 Nov 2020 17:24'	System	19 Nov 2020 22:24:14

US3172469

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:32:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '19 Nov 2020 12:00'	System	18 Nov 2020 16:16:30

US3172469

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:32:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '20 Nov 2020 11:59'	System	18 Nov 2020 16:16:30

US3172469

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
Data entry locked.	System	18 Nov 2020 16:16:30
User entered 'Day 3'	System	18 Nov 2020 16:16:30

US3172469

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:32:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-20T14:53:19', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'b591cc42-9b53-4748-b1e1-bcdab2420658'	System	20 Nov 2020 19:53:46
User entered 'Yes (Y)'	System	20 Nov 2020 19:53:46

US3172469

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:32:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-20T14:53:35', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'b591cc42-9b53-4748-b1e1-bcdab2420658'	System	20 Nov 2020 19:53:46
User entered '95.3'	System	20 Nov 2020 19:53:46

US3172469

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-20T14:53:40', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'b591cc42-9b53-4748-b1e1-bcdab2420658'	System	20 Nov 2020 19:53:46
User entered 'No (N)'	System	20 Nov 2020 19:53:46

US3172469

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:32:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-20T14:53:43', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'b591cc42-9b53-4748-b1e1-bcdab2420658'	System	20 Nov 2020 19:53:46
User entered '20 Nov 2020 14:53'	System	20 Nov 2020 19:53:46

US3172469

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:32:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '20 Nov 2020 12:00'	System	18 Nov 2020 16:16:30

US3172469

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:32:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '21 Nov 2020 11:59'	System	18 Nov 2020 16:16:30

US3172469

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
Data entry locked.	System	18 Nov 2020 16:16:30
User entered 'Day 4'	System	18 Nov 2020 16:16:30

US3172469

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:32:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-21T14:23:18', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '0ee19650-3cf1-4bc3-bd64-eba4975d0dfc'	System	21 Nov 2020 19:23:33
User entered 'Yes (Y)'	System	21 Nov 2020 19:23:33

US3172469

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:32:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-21T14:23:26', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '0ee19650-3cf1-4bc3-bd64-eba4975d0dfc'	System	21 Nov 2020 19:23:33
User entered '96.4'	System	21 Nov 2020 19:23:33

US3172469

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-21T14:23:29', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '0ee19650-3cf1-4bc3-bd64-eba4975d0dfc'	System	21 Nov 2020 19:23:33
User entered 'No (N)'	System	21 Nov 2020 19:23:33

US3172469

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:32:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-21T14:23:32', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '0ee19650-3cf1-4bc3-bd64-eba4975d0dfc'	System	21 Nov 2020 19:23:33
User entered '21 Nov 2020 14:23'	System	21 Nov 2020 19:23:33

US3172469

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:32:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '21 Nov 2020 12:00'	System	18 Nov 2020 16:16:30

US3172469

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:32:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '22 Nov 2020 11:59'	System	18 Nov 2020 16:16:30

US3172469

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
Data entry locked.	System	18 Nov 2020 16:16:30
User entered 'Day 5'	System	18 Nov 2020 16:16:30

US3172469

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:32:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14

US3172469

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:32:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14

US3172469

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14

US3172469

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14

US3172469

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:32:09

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14

US3172469

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:32:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14

US3172469

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:32:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '22 Nov 2020 12:00'	System	18 Nov 2020 16:16:30

US3172469

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:32:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '23 Nov 2020 11:59'	System	18 Nov 2020 16:16:30

US3172469

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
Data entry locked.	System	18 Nov 2020 16:16:30
User entered 'Day 6'	System	18 Nov 2020 16:16:30

US3172469

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:32:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-23T16:23:46', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '5eeffc1-0668-4e84-bef7-242600b433cc'	System	23 Nov 2020 21:24:13
User entered 'Yes (Y)'	System	23 Nov 2020 21:24:13

US3172469

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:32:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-23T16:24:02', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '5eeffc1-0668-4e84-bef7-242600b433cc'	System	23 Nov 2020 21:24:13
User entered '96.3'	System	23 Nov 2020 21:24:13

US3172469

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-23T16:24:08', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '5eeffc1-0668-4e84-bef7-242600b433cc'	System	23 Nov 2020 21:24:13
User entered 'No (N)'	System	23 Nov 2020 21:24:13

US3172469

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:32:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-23T16:24:12', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '5eeffc1-0668-4e84-bef7-242600b433cc'	System	23 Nov 2020 21:24:13
User entered '23 Nov 2020 16:24'	System	23 Nov 2020 21:24:13

US3172469

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:32:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '23 Nov 2020 12:00'	System	18 Nov 2020 16:16:30

US3172469

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:32:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '24 Nov 2020 11:59'	System	18 Nov 2020 16:16:30

US3172469

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
Data entry locked.	System	18 Nov 2020 16:16:30
User entered 'Day 7'	System	18 Nov 2020 16:16:30

US3172469

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:32:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-24T17:31:31', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '1629ca7c-40b1-4cc5-a396-6004ad557cdd'	System	24 Nov 2020 22:31:48
User entered 'Yes (Y)'	System	24 Nov 2020 22:31:48

US3172469

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:32:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-24T17:31:39', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '1629ca7c-40b1-4cc5-a396-6004ad557cdd' User entered '96.5'	System	24 Nov 2020 22:31:48
	System	24 Nov 2020 22:31:48

US3172469

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-24T17:31:43', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '1629ca7c-40b1-4cc5-a396-6004ad557cdd'	System	24 Nov 2020 22:31:48
User entered 'No (N)'	System	24 Nov 2020 22:31:48

US3172469

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:32:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-24T17:31:46', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '1629ca7c-40b1-4cc5-a396-6004ad557cdd'	System	24 Nov 2020 22:31:48
User entered '24 Nov 2020 17:31'	System	24 Nov 2020 22:31:48

US3172469

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:32:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '24 Nov 2020 12:00'	System	18 Nov 2020 16:16:30

US3172469

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:32:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '25 Nov 2020 11:59'	System	18 Nov 2020 16:16:30

US3172469

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
Data entry locked.	System	18 Nov 2020 16:16:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Nov 2020 16:16:30

US3172469

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:32:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-18T11:41:39', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '0672af78-c515-4fea-acc3-928430185cda'	System	18 Nov 2020 16:41:53
User entered 'None (1)'	System	18 Nov 2020 16:41:53

US3172469

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-18T11:41:42', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '0672af78-c515-4fea-acc3-928430185cda'	System	18 Nov 2020 16:41:53
User entered 'No (N)'	System	18 Nov 2020 16:41:53

US3172469

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-18T11:41:44', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '0672af78-c515-4fea-acc3-928430185cda'	System	18 Nov 2020 16:41:53
User entered 'No (N)'	System	18 Nov 2020 16:41:53

US3172469

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:32:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-18T11:41:47', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '0672af78-c515-4fea-acc3-928430185cda'	System	18 Nov 2020 16:41:53
User entered 'None (1)'	System	18 Nov 2020 16:41:53

US3172469

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:32:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-18T11:41:50', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '0672af78-c515-4fea-acc3-928430185cda' User entered '18 Nov 2020 11:41'	System	18 Nov 2020 16:41:53
	System	18 Nov 2020 16:41:53

US3172469

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:32:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '18 Nov 2020 11:24'	System	18 Nov 2020 16:16:30

US3172469

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:32:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '18 Nov 2020 13:54'	System	18 Nov 2020 16:16:30

US3172469

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
Data entry locked.	System	18 Nov 2020 16:16:30
User entered 'Day 1, after vaccination (at home)'	System	18 Nov 2020 16:16:30

US3172469

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:32:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-18T18:02:23', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'a24bcd06-ebaa-462f-822e-4bd4cd3fc21a'	System	18 Nov 2020 23:02:48
User entered 'None (1)'	System	18 Nov 2020 23:02:48

US3172469

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-18T18:02:29', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'a24bcd06-ebaa-462f-822e-4bd4cd3fc21a'	System	18 Nov 2020 23:02:48
User entered 'No (N)'	System	18 Nov 2020 23:02:48

US3172469

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-18T18:02:34', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'a24bcd06-ebaa-462f-822e-4bd4cd3fc21a'	System	18 Nov 2020 23:02:48
User entered 'No (N)'	System	18 Nov 2020 23:02:48

US3172469

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:32:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-18T18:02:39', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'a24bcd06-ebaa-462f-822e-4bd4cd3fc21a'	System	18 Nov 2020 23:02:48
User entered 'None (1)'	System	18 Nov 2020 23:02:48

US3172469

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:32:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-18T18:02:45', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'a24bcd06-ebaa-462f-822e-4bd4cd3fc21a'	System	18 Nov 2020 23:02:48
User entered '18 Nov 2020 18:02'	System	18 Nov 2020 23:02:48

US3172469

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:32:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '18 Nov 2020 14:49'	System	18 Nov 2020 16:16:30

US3172469

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:32:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '19 Nov 2020 11:59'	System	18 Nov 2020 16:16:30

US3172469

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
Data entry locked.	System	18 Nov 2020 16:16:30
User entered 'Day 2'	System	18 Nov 2020 16:16:30

US3172469

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:32:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-19T17:24:16', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '44cf9fb9-7016-4a11-ae0d-f6405e2f7fce'	System	19 Nov 2020 22:24:33
User entered 'None (1)'	System	19 Nov 2020 22:24:33

US3172469

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-19T17:24:19', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '44cf9fb9-7016-4a11-ae0d-f6405e2f7fce'	System	19 Nov 2020 22:24:33
User entered 'No (N)'	System	19 Nov 2020 22:24:33

US3172469

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-19T17:24:24', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '44cf9fb9-7016-4a11-ae0d-f6405e2f7fce'	System	19 Nov 2020 22:24:33
User entered 'No (N)'	System	19 Nov 2020 22:24:33

US3172469

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:32:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-19T17:24:28', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '44cf9fb9-7016-4a11-ae0d-f6405e2f7fce'	System	19 Nov 2020 22:24:33
User entered 'None (1)'	System	19 Nov 2020 22:24:33

US3172469

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:32:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-19T17:24:31', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '44cf9fb9-7016-4a11-ae0d-f6405e2f7fce' User entered '19 Nov 2020 17:24'	System	19 Nov 2020 22:24:33
	System	19 Nov 2020 22:24:33

US3172469

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:32:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '19 Nov 2020 12:00'	System	18 Nov 2020 16:16:30

US3172469

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:32:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '20 Nov 2020 11:59'	System	18 Nov 2020 16:16:30

US3172469

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
Data entry locked.	System	18 Nov 2020 16:16:30
User entered 'Day 3'	System	18 Nov 2020 16:16:30

US3172469

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:32:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-20T14:53:48', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '6e3e9b41-0a10-477d-8c00-d54770e92beb'	System	20 Nov 2020 19:54:07
User entered 'None (1)'	System	20 Nov 2020 19:54:07

US3172469

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-20T14:53:54', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '6e3e9b41-0a10-477d-8c00-d54770e92beb'	System	20 Nov 2020 19:54:07
User entered 'No (N)'	System	20 Nov 2020 19:54:07

US3172469

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-20T14:53:57', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '6e3e9b41-0a10-477d-8c00-d54770e92beb'	System	20 Nov 2020 19:54:07
User entered 'No (N)'	System	20 Nov 2020 19:54:07

US3172469

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:32:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-20T14:54:00', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '6e3e9b41-0a10-477d-8c00-d54770e92beb'	System	20 Nov 2020 19:54:07
User entered 'None (1)'	System	20 Nov 2020 19:54:07

US3172469

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:32:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-20T14:54:03', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '6e3e9b41-0a10-477d-8c00-d54770e92beb' User entered '20 Nov 2020 14:54'	System	20 Nov 2020 19:54:07
	System	20 Nov 2020 19:54:07

US3172469

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:32:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '20 Nov 2020 12:00'	System	18 Nov 2020 16:16:30

US3172469

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:32:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '21 Nov 2020 11:59'	System	18 Nov 2020 16:16:30

US3172469

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
Data entry locked.	System	18 Nov 2020 16:16:30
User entered 'Day 4'	System	18 Nov 2020 16:16:30

US3172469

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:32:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-21T14:23:36', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'bd97a680-b3c3-46a2-8936-cd2b02362204'	System	21 Nov 2020 19:23:50
User entered 'None (1)'	System	21 Nov 2020 19:23:50

US3172469

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-21T14:23:39', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'bd97a680-b3c3-46a2-8936-cd2b02362204'	System	21 Nov 2020 19:23:50
User entered 'No (N)'	System	21 Nov 2020 19:23:50

US3172469

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-21T14:23:41', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'bd97a680-b3c3-46a2-8936-cd2b02362204'	System	21 Nov 2020 19:23:50
User entered 'No (N)'	System	21 Nov 2020 19:23:50

US3172469

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:32:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-21T14:23:43', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'bd97a680-b3c3-46a2-8936-cd2b02362204'	System	21 Nov 2020 19:23:50
User entered 'None (1)'	System	21 Nov 2020 19:23:50

US3172469

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:32:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-21T14:23:46', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'bd97a680-b3c3-46a2-8936-cd2b02362204'	System	21 Nov 2020 19:23:50
User entered '21 Nov 2020 14:23'	System	21 Nov 2020 19:23:50

US3172469

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:32:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '21 Nov 2020 12:00'	System	18 Nov 2020 16:16:30

US3172469

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:32:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '22 Nov 2020 11:59'	System	18 Nov 2020 16:16:30

US3172469

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
Data entry locked.	System	18 Nov 2020 16:16:30
User entered 'Day 5'	System	18 Nov 2020 16:16:30

US3172469

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:32:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14

US3172469

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14

US3172469

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:32:09

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14

US3172469

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14

US3172469

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:32:09

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14

US3172469

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:32:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14

US3172469

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:32:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14

US3172469

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:32:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '22 Nov 2020 12:00'	System	18 Nov 2020 16:16:30

US3172469

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:32:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '23 Nov 2020 11:59'	System	18 Nov 2020 16:16:30

US3172469

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
Data entry locked.	System	18 Nov 2020 16:16:30
User entered 'Day 6'	System	18 Nov 2020 16:16:30

US3172469

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:32:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-23T16:24:16', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'fffb334d-5931-43d8-b4b5-e22be2548ceb'	System	23 Nov 2020 21:24:29
User entered 'None (1)'	System	23 Nov 2020 21:24:29

US3172469

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-23T16:24:18', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'fffb334d-5931-43d8-b4b5-e22be2548ceb'	System	23 Nov 2020 21:24:29
User entered 'No (N)'	System	23 Nov 2020 21:24:29

US3172469

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-23T16:24:20', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'fffb334d-5931-43d8-b4b5-e22be2548ceb'	System	23 Nov 2020 21:24:29
User entered 'No (N)'	System	23 Nov 2020 21:24:29

US3172469

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:32:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-23T16:24:22', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'fffb334d-5931-43d8-b4b5-e22be2548ceb'	System	23 Nov 2020 21:24:29
User entered 'None (1)'	System	23 Nov 2020 21:24:29

US3172469

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:32:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-23T16:24:25', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'fffb334d-5931-43d8-b4b5-e22be2548ceb' User entered '23 Nov 2020 16:24'	System	23 Nov 2020 21:24:29
	System	23 Nov 2020 21:24:29

US3172469

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:32:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '23 Nov 2020 12:00'	System	18 Nov 2020 16:16:30

US3172469

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:32:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '24 Nov 2020 11:59'	System	18 Nov 2020 16:16:30

US3172469

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
Data entry locked.	System	18 Nov 2020 16:16:30
User entered 'Day 7'	System	18 Nov 2020 16:16:30

US3172469

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:32:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-24T17:31:50', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '06254f8d-d0b4-4d78-b10b-7919a83466fa'	System	24 Nov 2020 22:32:07
User entered 'None (1)'	System	24 Nov 2020 22:32:07

US3172469

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-24T17:31:53', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '06254f8d-d0b4-4d78-b10b-7919a83466fa'	System	24 Nov 2020 22:32:07
User entered 'No (N)'	System	24 Nov 2020 22:32:07

US3172469

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-24T17:31:56', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '06254f8d-d0b4-4d78-b10b-7919a83466fa'	System	24 Nov 2020 22:32:07
User entered 'No (N)'	System	24 Nov 2020 22:32:07

US3172469

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:32:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-24T17:31:58', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '06254f8d-d0b4-4d78-b10b-7919a83466fa'	System	24 Nov 2020 22:32:07
User entered 'None (1)'	System	24 Nov 2020 22:32:07

US3172469

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:32:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-24T17:32:02', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '06254f8d-d0b4-4d78-b10b-7919a83466fa'	System	24 Nov 2020 22:32:07
User entered '24 Nov 2020 17:32'	System	24 Nov 2020 22:32:07

US3172469

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:32:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '24 Nov 2020 12:00'	System	18 Nov 2020 16:16:30

US3172469

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:32:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '25 Nov 2020 11:59'	System	18 Nov 2020 16:16:30

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
Data entry locked.	System	18 Nov 2020 16:16:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Nov 2020 16:16:30

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:32:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-18T11:41:55', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '88c09e34-4088-4904-834d-461989bb6cee'	System	18 Nov 2020 16:42:20
User entered 'None (0)'	System	18 Nov 2020 16:42:20

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:32:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-18T11:41:58', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '88c09e34-4088-4904-834d-461989bb6cee'	System	18 Nov 2020 16:42:20
User entered 'None (0)'	System	18 Nov 2020 16:42:20

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:32:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-18T11:42:00', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '88c09e34-4088-4904-834d-461989bb6cee'	System	18 Nov 2020 16:42:20
User entered 'None (0)'	System	18 Nov 2020 16:42:20

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:32:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-18T11:42:03', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '88c09e34-4088-4904-834d-461989bb6cee'	System	18 Nov 2020 16:42:20
User entered 'None (0)'	System	18 Nov 2020 16:42:20

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:32:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-18T11:42:06', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '88c09e34-4088-4904-834d-461989bb6cee'	System	18 Nov 2020 16:42:20
User entered 'None (0)'	System	18 Nov 2020 16:42:20

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:32:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-18T11:42:09', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '88c09e34-4088-4904-834d-461989bb6cee'	System	18 Nov 2020 16:42:20
User entered 'None (0)'	System	18 Nov 2020 16:42:20

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-18T11:42:12', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '88c09e34-4088-4904-834d-461989bb6cee'	System	18 Nov 2020 16:42:20
User entered 'No (N)'	System	18 Nov 2020 16:42:20

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:32:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-18T11:42:15', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '88c09e34-4088-4904-834d-461989bb6cee' User entered '18 Nov 2020 11:42'	System	18 Nov 2020 16:42:20
	System	18 Nov 2020 16:42:20

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:32:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '18 Nov 2020 11:24'	System	18 Nov 2020 16:16:30

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:32:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '18 Nov 2020 13:54'	System	18 Nov 2020 16:16:30

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
Data entry locked.	System	18 Nov 2020 16:16:30
User entered 'Day 1, after vaccination (at home)'	System	18 Nov 2020 16:16:30

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:32:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-18T18:02:51', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '05febb3-30fe-4cae-b7dd-8309d06b989d'	System	18 Nov 2020 23:03:24
User entered 'None (0)'	System	18 Nov 2020 23:03:24

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:32:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-18T18:02:55', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '05febb3-30fe-4cae-b7dd-8309d06b989d'	System	18 Nov 2020 23:03:24
User entered 'None (0)'	System	18 Nov 2020 23:03:24

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:32:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-18T18:03:02', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '05febb3-30fe-4cae-b7dd-8309d06b989d'	System	18 Nov 2020 23:03:24
User entered 'None (0)'	System	18 Nov 2020 23:03:24

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:32:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-18T18:03:06', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '05febb3-30fe-4cae-b7dd-8309d06b989d'	System	18 Nov 2020 23:03:24
User entered 'None (0)'	System	18 Nov 2020 23:03:24

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:32:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-18T18:03:10', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '05febb3-30fe-4cae-b7dd-8309d06b989d'	System	18 Nov 2020 23:03:24
User entered 'None (0)'	System	18 Nov 2020 23:03:24

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:32:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-18T18:03:14', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '05feebb3-30fe-4cae-b7dd-8309d06b989d'	System	18 Nov 2020 23:03:24
User entered 'None (0)'	System	18 Nov 2020 23:03:24

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-18T18:03:18', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '05febb3-30fe-4cae-b7dd-8309d06b989d'	System	18 Nov 2020 23:03:24
User entered 'No (N)'	System	18 Nov 2020 23:03:24

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:32:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-18T18:03:21', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '05feebb3-30fe-4cae-b7dd-8309d06b989d'	System	18 Nov 2020 23:03:24
User entered '18 Nov 2020 18:03'	System	18 Nov 2020 23:03:24

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:32:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '18 Nov 2020 14:49'	System	18 Nov 2020 16:16:30

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:32:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '19 Nov 2020 11:59'	System	18 Nov 2020 16:16:30

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
Data entry locked.	System	18 Nov 2020 16:16:30
User entered 'Day 2'	System	18 Nov 2020 16:16:30

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:32:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-19T17:24:37', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '8249379d-2d8a-4202-af36-12444b02c472'	System	19 Nov 2020 22:25:03
User entered 'None (0)'	System	19 Nov 2020 22:25:03

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:32:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-19T17:24:40', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '8249379d-2d8a-4202-af36-12444b02c472'	System	19 Nov 2020 22:25:03
User entered 'None (0)'	System	19 Nov 2020 22:25:03

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:32:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-19T17:24:43', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '8249379d-2d8a-4202-af36-12444b02c472'	System	19 Nov 2020 22:25:03
User entered 'None (0)'	System	19 Nov 2020 22:25:03

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:32:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-19T17:24:45', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '8249379d-2d8a-4202-af36-12444b02c472'	System	19 Nov 2020 22:25:03
User entered 'None (0)'	System	19 Nov 2020 22:25:03

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:32:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-19T17:24:47', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '8249379d-2d8a-4202-af36-12444b02c472'	System	19 Nov 2020 22:25:03
User entered 'None (0)'	System	19 Nov 2020 22:25:03

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:32:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-19T17:24:50', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '8249379d-2d8a-4202-af36-12444b02c472'	System	19 Nov 2020 22:25:03
User entered 'None (0)'	System	19 Nov 2020 22:25:03

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-19T17:24:56', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '8249379d-2d8a-4202-af36-12444b02c472'	System	19 Nov 2020 22:25:03
User entered 'No (N)'	System	19 Nov 2020 22:25:03

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:32:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-19T17:24:59', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '8249379d-2d8a-4202-af36-12444b02c472'	System	19 Nov 2020 22:25:03
User entered '19 Nov 2020 17:24'	System	19 Nov 2020 22:25:03

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:32:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '19 Nov 2020 12:00'	System	18 Nov 2020 16:16:30

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:32:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '20 Nov 2020 11:59'	System	18 Nov 2020 16:16:30

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
Data entry locked.	System	18 Nov 2020 16:16:30
User entered 'Day 3'	System	18 Nov 2020 16:16:30

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:32:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-20T14:54:08', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '8e4b89c5-88a1-450d-9e69-4235c47f9a4a'	System	20 Nov 2020 19:54:28
User entered 'None (0)'	System	20 Nov 2020 19:54:28

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:32:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-20T14:54:10', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '8e4b89c5-88a1-450d-9e69-4235c47f9a4a'	System	20 Nov 2020 19:54:28
User entered 'None (0)'	System	20 Nov 2020 19:54:28

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:32:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-20T14:54:13', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '8e4b89c5-88a1-450d-9e69-4235c47f9a4a'	System	20 Nov 2020 19:54:28
User entered 'None (0)'	System	20 Nov 2020 19:54:28

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:32:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-20T14:54:15', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '8e4b89c5-88a1-450d-9e69-4235c47f9a4a'	System	20 Nov 2020 19:54:28
User entered 'None (0)'	System	20 Nov 2020 19:54:28

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:32:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-20T14:54:18', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '8e4b89c5-88a1-450d-9e69-4235c47f9a4a'	System	20 Nov 2020 19:54:28
User entered 'None (0)'	System	20 Nov 2020 19:54:28

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:32:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-20T14:54:20', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '8e4b89c5-88a1-450d-9e69-4235c47f9a4a'	System	20 Nov 2020 19:54:28
User entered 'None (0)'	System	20 Nov 2020 19:54:28

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-20T14:54:23', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '8e4b89c5-88a1-450d-9e69-4235c47f9a4a'	System	20 Nov 2020 19:54:28
User entered 'No (N)'	System	20 Nov 2020 19:54:28

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:32:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-20T14:54:25', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '8e4b89c5-88a1-450d-9e69-4235c47f9a4a'	System	20 Nov 2020 19:54:28
User entered '20 Nov 2020 14:54'	System	20 Nov 2020 19:54:28

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:32:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '20 Nov 2020 12:00'	System	18 Nov 2020 16:16:30

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:32:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '21 Nov 2020 11:59'	System	18 Nov 2020 16:16:30

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
Data entry locked.	System	18 Nov 2020 16:16:30
User entered 'Day 4'	System	18 Nov 2020 16:16:30

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:32:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-21T14:23:50', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '17351ccf-da1d-447b-8343-890dc1d22baf'	System	21 Nov 2020 19:24:07
User entered 'None (0)'	System	21 Nov 2020 19:24:07

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:32:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-21T14:23:52', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '17351ccf-da1d-447b-8343-890dc1d22baf'	System	21 Nov 2020 19:24:07
User entered 'None (0)'	System	21 Nov 2020 19:24:07

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:32:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-21T14:23:54', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '17351ccf-da1d-447b-8343-890dc1d22baf'	System	21 Nov 2020 19:24:07
User entered 'None (0)'	System	21 Nov 2020 19:24:07

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:32:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-21T14:23:56', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '17351ccf-da1d-447b-8343-890dc1d22baf'	System	21 Nov 2020 19:24:07
User entered 'None (0)'	System	21 Nov 2020 19:24:07

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:32:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-21T14:23:58', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '17351ccf-da1d-447b-8343-890dc1d22baf'	System	21 Nov 2020 19:24:07
User entered 'None (0)'	System	21 Nov 2020 19:24:07

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:32:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-21T14:24:01', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '17351ccf-da1d-447b-8343-890dc1d22baf'	System	21 Nov 2020 19:24:07
User entered 'None (0)'	System	21 Nov 2020 19:24:07

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-21T14:24:03', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '17351ccf-da1d-447b-8343-890dc1d22baf'	System	21 Nov 2020 19:24:07
User entered 'No (N)'	System	21 Nov 2020 19:24:07

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:32:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-21T14:24:05', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '17351ccf-da1d-447b-8343-890dc1d22baf'	System	21 Nov 2020 19:24:07
User entered '21 Nov 2020 14:24'	System	21 Nov 2020 19:24:07

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:32:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '21 Nov 2020 12:00'	System	18 Nov 2020 16:16:30

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:32:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '22 Nov 2020 11:59'	System	18 Nov 2020 16:16:30

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
Data entry locked.	System	18 Nov 2020 16:16:30
User entered 'Day 5'	System	18 Nov 2020 16:16:30

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:32:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:32:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:32:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:32:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:32:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:32:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:32:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:32:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '22 Nov 2020 12:00'	System	18 Nov 2020 16:16:30

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:32:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '23 Nov 2020 11:59'	System	18 Nov 2020 16:16:30

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
Data entry locked.	System	18 Nov 2020 16:16:30
User entered 'Day 6'	System	18 Nov 2020 16:16:30

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:32:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-23T16:24:29', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'c3b99165-cafa-42ed-924c-77463c409cbc'	System	23 Nov 2020 21:24:47
User entered 'None (0)'	System	23 Nov 2020 21:24:47

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:32:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-23T16:24:32', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'c3b99165-cafa-42ed-924c-77463c409cbc'	System	23 Nov 2020 21:24:47
User entered 'None (0)'	System	23 Nov 2020 21:24:47

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:32:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-23T16:24:34', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'c3b99165-cafa-42ed-924c-77463c409cbc'	System	23 Nov 2020 21:24:47
User entered 'None (0)'	System	23 Nov 2020 21:24:47

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:32:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-23T16:24:36', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'c3b99165-cafa-42ed-924c-77463c409cbc'	System	23 Nov 2020 21:24:47
User entered 'None (0)'	System	23 Nov 2020 21:24:47

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:32:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-23T16:24:38', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'c3b99165-cafa-42ed-924c-77463c409cbc'	System	23 Nov 2020 21:24:47
User entered 'None (0)'	System	23 Nov 2020 21:24:47

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:32:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-23T16:24:40', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'c3b99165-cafa-42ed-924c-77463c409cbc'	System	23 Nov 2020 21:24:47
User entered 'None (0)'	System	23 Nov 2020 21:24:47

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-23T16:24:43', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'c3b99165-cafa-42ed-924c-77463c409cbc'	System	23 Nov 2020 21:24:47
User entered 'No (N)'	System	23 Nov 2020 21:24:47

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:32:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-23T16:24:46', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'c3b99165-cafa-42ed-924c-77463c409cbc'	System	23 Nov 2020 21:24:47
User entered '23 Nov 2020 16:24'	System	23 Nov 2020 21:24:47

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:32:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '23 Nov 2020 12:00'	System	18 Nov 2020 16:16:30

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:32:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '24 Nov 2020 11:59'	System	18 Nov 2020 16:16:30

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
Data entry locked.	System	18 Nov 2020 16:16:30
User entered 'Day 7'	System	18 Nov 2020 16:16:30

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:32:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-24T17:32:06', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '636e0596-4e8a-497e-82e1-11050206e4a8'	System	24 Nov 2020 22:32:25
User entered 'None (0)'	System	24 Nov 2020 22:32:25

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:32:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-24T17:32:08', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '636e0596-4e8a-497e-82e1-11050206e4a8'	System	24 Nov 2020 22:32:25
User entered 'None (0)'	System	24 Nov 2020 22:32:25

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:32:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-24T17:32:11', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '636e0596-4e8a-497e-82e1-11050206e4a8'	System	24 Nov 2020 22:32:25
User entered 'None (0)'	System	24 Nov 2020 22:32:25

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:32:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-24T17:32:13', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '636e0596-4e8a-497e-82e1-11050206e4a8'	System	24 Nov 2020 22:32:25
User entered 'None (0)'	System	24 Nov 2020 22:32:25

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:32:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-24T17:32:16', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '636e0596-4e8a-497e-82e1-11050206e4a8'	System	24 Nov 2020 22:32:25
User entered 'None (0)'	System	24 Nov 2020 22:32:25

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:32:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-24T17:32:18', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '636e0596-4e8a-497e-82e1-11050206e4a8'	System	24 Nov 2020 22:32:25
User entered 'None (0)'	System	24 Nov 2020 22:32:25

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-24T17:32:21', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '636e0596-4e8a-497e-82e1-11050206e4a8'	System	24 Nov 2020 22:32:25
User entered 'No (N)'	System	24 Nov 2020 22:32:25

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:32:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-11-24T17:32:23', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '636e0596-4e8a-497e-82e1-11050206e4a8'	System	24 Nov 2020 22:32:25
User entered '24 Nov 2020 17:32'	System	24 Nov 2020 22:32:25

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:32:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '24 Nov 2020 12:00'	System	18 Nov 2020 16:16:30

US3172469

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:32:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:33:14
User entered '25 Nov 2020 11:59'	System	18 Nov 2020 16:16:30

US3172469

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:09

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	25 Nov 2020 19:40:15

US3172469

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '25 Nov 2020'	Mariete Rendon (b) (4) (b) (4)	25 Nov 2020 19:40:15

US3172469

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:09

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Contact Made (CONTACT MADE)'	Mariete Rendon (b) (4) (b) (4)	25 Nov 2020 19:40:15

US3172469

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:09

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered empty.	Mariete Rendon (b) (4) (b) (4)	25 Nov 2020 19:40:15

US3172469

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	25 Nov 2020 19:40:24

US3172469

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:09

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User entered 'I'	System	25 Nov 2020 19:40:24

US3172469

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:09

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	04 Dec 2020 18:00:15

US3172469

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '04 Dec 2020'	Jessie Downs (b) (4) (b) (4)	04 Dec 2020 18:00:15

US3172469

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:09

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Contact Not Made (CONTACT NOT MADE)'	Jessie Downs (b) (4) (b) (4)	04 Dec 2020 18:00:15

US3172469

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:09

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'UNABLE TO CONTACT SUBECT. SUBJECT'S VOICEMAIL IS NOT SET UP. SPOKE TO EMERGENCY CONTACT #1 BUT HAS NOT BEEN ABLE TO CONTACT SUBJECT. EMERCENCY CONTACT #2 WRONG NUMBER.'	Jessie Downs (b) (4) (b) (4)	04 Dec 2020 18:00:15

US3172469

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	04 Dec 2020 18:00:19

US3172469

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:09

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User entered '1'	System	04 Dec 2020 18:00:19

US3172469

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:09

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	11 Dec 2020 15:55:44
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	11 Dec 2020 15:55:38
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	11 Dec 2020 15:55:38

US3172469

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '11 Dec 2020'	Jessie Downs (b) (4) (b) (4)	11 Dec 2020 15:55:38

US3172469

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:09

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Contact Not Made (CONTACT NOT MADE)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	11 Dec 2020 15:55:44
User entered empty.	Jessie Downs (b) (4) (b) (4)	11 Dec 2020 15:55:38

US3172469

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:09

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Unable to contact subject. Contacted emergency contact who reported subject is hospitalized in Jackson Memorial Hospital.'	Jessie Downs (b) (4) (b) (4)	11 Dec 2020 15:55:38

US3172469

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	11 Dec 2020 16:43:05

US3172469

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:09

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User entered '1'	System	11 Dec 2020 16:43:05

US3172469

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:32:09

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	18 Jan 2021 22:23:54

US3172469

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Jan 2021 22:23:54

US3172469

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Jan 2021 22:23:54

US3172469

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:32:09

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User entered 'VISIT3'	System	18 Jan 2021 22:23:54

US3172469

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	18 Jan 2021 22:23:50

US3172469

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Jan 2021 22:23:50

US3172469

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Jan 2021 22:23:50

US3172469

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User entered empty.	System	18 Jan 2021 22:23:50

US3172469

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:09

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Jan 2021 22:23:50

US3172469

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:09

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Jan 2021 22:23:50

US3172469

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:09

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Jan 2021 22:23:50

US3172469

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:09

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Jan 2021 22:23:50

US3172469

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:09

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User entered empty.	System	18 Jan 2021 22:23:50

US3172469

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Jan 2021 22:23:50

US3172469

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User entered empty.	System	18 Jan 2021 22:23:50

US3172469

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:09

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Jan 2021 22:23:50

US3172469

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User entered empty.	System	18 Jan 2021 22:23:50

US3172469

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:09

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Jan 2021 22:23:50

US3172469

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:09

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User entered empty.	System	18 Jan 2021 22:23:50

US3172469

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:09

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36

US3172469

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:32:09

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36

US3172469

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:32:09

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	18 Jan 2021 22:23:58

US3172469

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:32:09

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Jan 2021 22:23:58

US3172469

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:32:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	18 Jan 2021 22:24:02

US3172469

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:32:09

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Jan 2021 22:24:02

US3172469

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:32:09

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Jan 2021 22:24:02

US3172469

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:32:09

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User entered empty.	System	18 Jan 2021 22:24:02

US3172469

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	18 Jan 2021 14:00:00

US3172469

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:09

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User entered '1'	System	18 Jan 2021 14:00:00

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[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 (d910329ff6c2fe5f)', Time: '2020-12-18T15:35:17', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '71885b96-91ef-4573-ba70-43678f2cb015'	System	18 Dec 2020 20:35:45
User entered 'Yes (Y)'	System	18 Dec 2020 20:35:45

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

Have you been exposed to someone with 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 (d910329ff6c2fe5f)', Time: '2020-12-18T15:35:24', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '71885b96-91ef-4573-ba70-43678f2cb015'	System	18 Dec 2020 20:35:45
User entered 'No (N)'	System	18 Dec 2020 20:35:45

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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 (d910329ff6c2fe5f)', Time: '2020-12-18T15:35:29', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '71885b96-91ef-4573-ba70-43678f2cb015'	System	18 Dec 2020 20:35:45
User entered 'No (N)'	System	18 Dec 2020 20:35:45

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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 (d910329ff6c2fe5f)', Time: '2020-12-18T15:35:34', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '71885b96-91ef-4573-ba70-43678f2cb015'	System	18 Dec 2020 20:35:45
User entered 'No (N)'	System	18 Dec 2020 20:35:45

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2020-12-18T15:35:41', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '71885b96-91ef-4573-ba70-43678f2cb015'	System	18 Dec 2020 20:35:45
User entered '18 Dec 2020 15:35:41'	System	18 Dec 2020 20:35:45

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '18 Dec 2020 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '22 Dec 2020 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '25 Dec 2020 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '29 Dec 2020 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[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 (d910329ff6c2fe5f)', Time: '2021-01-01T08:42:01', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '0cb15fa8-8176-474f-a914-66d0d448ccc4'	System	01 Jan 2021 13:42:11
User entered 'No (N)'	System	01 Jan 2021 13:42:11

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

Have you been exposed to someone with 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 (d910329ff6c2fe5f)', Time: '2021-01-01T08:42:04', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '0cb15fa8-8176-474f-a914-66d0d448ccc4'	System	01 Jan 2021 13:42:11
User entered 'No (N)'	System	01 Jan 2021 13:42:11

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2021-01-01T08:42:09', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '0cb15fa8-8176-474f-a914-66d0d448ccc4'	System	01 Jan 2021 13:42:11
User entered '01 Jan 2021 08:42:09'	System	01 Jan 2021 13:42:11

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '01 Jan 2021 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '05 Jan 2021 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[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 (d910329ff6c2fe5f)', Time: '2021-01-11T08:32:28', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'ef0956c8-b279-4ed5-ad14-38ca86125837'	System	11 Jan 2021 13:32:38
User entered 'No (N)'	System	11 Jan 2021 13:32:38

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

Have you been exposed to someone with 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 (d910329ff6c2fe5f)', Time: '2021-01-11T08:32:31', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'ef0956c8-b279-4ed5-ad14-38ca86125837'	System	11 Jan 2021 13:32:38
User entered 'No (N)'	System	11 Jan 2021 13:32:38

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2021-01-11T08:32:35', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'ef0956c8-b279-4ed5-ad14-38ca86125837'	System	11 Jan 2021 13:32:38
User entered '11 Jan 2021 08:32:35'	System	11 Jan 2021 13:32:38

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '08 Jan 2021 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '12 Jan 2021 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[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 (d910329ff6c2fe5f)', Time: '2021-01-16T10:20:12', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'ae133070-657a-493c-a989-de8af092ec0c'	System	16 Jan 2021 15:20:23
User entered 'No (N)'	System	16 Jan 2021 15:20:23

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

Have you been exposed to someone with 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 (d910329ff6c2fe5f)', Time: '2021-01-16T10:20:15', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'ae133070-657a-493c-a989-de8af092ec0c'	System	16 Jan 2021 15:20:23
User entered 'No (N)'	System	16 Jan 2021 15:20:23

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2021-01-16T10:20:18', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'ae133070-657a-493c-a989-de8af092ec0c'	System	16 Jan 2021 15:20:23
User entered '16 Jan 2021 10:20:18'	System	16 Jan 2021 15:20:23

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '15 Jan 2021 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '19 Jan 2021 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[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 (d910329ff6c2fe5f)', Time: '2021-01-23T11:31:32', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'e5ac7b29-f523-4f21-a497-6ad87ebfb49b'	System	23 Jan 2021 16:31:47
User entered 'No (N)'	System	23 Jan 2021 16:31:47

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

Have you been exposed to someone with 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 (d910329ff6c2fe5f)', Time: '2021-01-23T11:31:40', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'e5ac7b29-f523-4f21-a497-6ad87ebfb49b'	System	23 Jan 2021 16:31:47
User entered 'No (N)'	System	23 Jan 2021 16:31:47

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2021-01-23T11:31:44', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'e5ac7b29-f523-4f21-a497-6ad87ebfb49b'	System	23 Jan 2021 16:31:47
User entered '23 Jan 2021 11:31:44'	System	23 Jan 2021 16:31:47

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '22 Jan 2021 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '26 Jan 2021 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[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 (d910329ff6c2fe5f)', Time: '2021-01-29T04:41:00', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'b1e68b4e-aa56-415e-b442-21de8495f8af'	System	29 Jan 2021 09:42:03
User entered 'Yes (Y)'	System	29 Jan 2021 09:42:03

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

Have you been exposed to someone with 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 (d910329ff6c2fe5f)', Time: '2021-01-29T04:41:52', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'b1e68b4e-aa56-415e-b442-21de8495f8af'	System	29 Jan 2021 09:42:03
User entered 'No (N)'	System	29 Jan 2021 09:42:03

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[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 (d910329ff6c2fe5f)', Time: '2021-01-29T04:41:14', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'b1e68b4e-aa56-415e-b442-21de8495f8af'	System	29 Jan 2021 09:42:03
User entered 'No (N)'	System	29 Jan 2021 09:42:03

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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 (d910329ff6c2fe5f)', Time: '2021-01-29T04:41:31', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'b1e68b4e-aa56-415e-b442-21de8495f8af'	System	29 Jan 2021 09:42:03
User entered 'No (N)'	System	29 Jan 2021 09:42:03

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2021-01-29T04:41:58', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'b1e68b4e-aa56-415e-b442-21de8495f8af' User entered '29 Jan 2021 04:41:58'	System	29 Jan 2021 09:42:03

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '29 Jan 2021 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '02 Feb 2021 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[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 (d910329ff6c2fe5f)', Time: '2021-02-05T10:17:51', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'd960e310-22d0-4685-81f5-791513cb5099'	System	05 Feb 2021 15:18:09
User entered 'No (N)'	System	05 Feb 2021 15:18:09

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

Have you been exposed to someone with 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 (d910329ff6c2fe5f)', Time: '2021-02-05T10:17:54', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'd960e310-22d0-4685-81f5-791513cb5099'	System	05 Feb 2021 15:18:09
User entered 'No (N)'	System	05 Feb 2021 15:18:09

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2021-02-05T10:18:05', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'd960e310-22d0-4685-81f5-791513cb5099'	System	05 Feb 2021 15:18:09
User entered '05 Feb 2021 10:18:05'	System	05 Feb 2021 15:18:09

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '05 Feb 2021 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '09 Feb 2021 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[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 (d910329ff6c2fe5f)', Time: '2021-02-12T08:41:39', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '37a7928b-7082-4cf8-a9b7-131b83325ac6'	System	12 Feb 2021 13:41:52
User entered 'No (N)'	System	12 Feb 2021 13:41:52

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

Have you been exposed to someone with 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 (d910329ff6c2fe5f)', Time: '2021-02-12T08:41:42', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '37a7928b-7082-4cf8-a9b7-131b83325ac6'	System	12 Feb 2021 13:41:52
User entered 'No (N)'	System	12 Feb 2021 13:41:52

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2021-02-12T08:41:49', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '37a7928b-7082-4cf8-a9b7-131b83325ac6'	System	12 Feb 2021 13:41:52
User entered '12 Feb 2021 08:41:49'	System	12 Feb 2021 13:41:52

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '12 Feb 2021 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '16 Feb 2021 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[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 (d910329ff6c2fe5f)', Time: '2021-02-19T09:38:24', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'ea4f3cf5-5f8b-436d-86ee-7e886d46db9b'	System	19 Feb 2021 14:38:40
User entered 'No (N)'	System	19 Feb 2021 14:38:40

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

Have you been exposed to someone with 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 (d910329ff6c2fe5f)', Time: '2021-02-19T09:38:30', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'ea4f3cf5-5f8b-436d-86ee-7e886d46db9b'	System	19 Feb 2021 14:38:40
User entered 'No (N)'	System	19 Feb 2021 14:38:40

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2021-02-19T09:38:36', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'ea4f3cf5-5f8b-436d-86ee-7e886d46db9b'	System	19 Feb 2021 14:38:40
User entered '19 Feb 2021 09:38:36'	System	19 Feb 2021 14:38:40

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '19 Feb 2021 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '23 Feb 2021 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '26 Feb 2021 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '02 Mar 2021 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[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 (d910329ff6c2fe5f)', Time: '2021-03-09T12:00:36', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '80d53517-4a8a-420f-80d8-fc0b4582a4fd'	System	09 Mar 2021 17:02:28
User entered 'No (N)'	System	09 Mar 2021 17:02:28

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

Have you been exposed to someone with 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 (d910329ff6c2fe5f)', Time: '2021-03-09T12:00:39', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '80d53517-4a8a-420f-80d8-fc0b4582a4fd'	System	09 Mar 2021 17:02:28
User entered 'No (N)'	System	09 Mar 2021 17:02:28

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2021-03-09T12:00:42', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '80d53517-4a8a-420f-80d8-fc0b4582a4fd'	System	09 Mar 2021 17:02:28
User entered '09 Mar 2021 12:00:42'	System	09 Mar 2021 17:02:28

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '05 Mar 2021 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '09 Mar 2021 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[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 (d910329ff6c2fe5f)', Time: '2021-03-14T17:24:29', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '9233b197-071a-48ef-a94e-e216d75f5255'	System	14 Mar 2021 21:24:56
User entered 'Yes (Y)'	System	14 Mar 2021 21:24:56

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

Have you been exposed to someone with 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 (d910329ff6c2fe5f)', Time: '2021-03-14T17:24:36', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '9233b197-071a-48ef-a94e-e216d75f5255'	System	14 Mar 2021 21:24:56
User entered 'No (N)'	System	14 Mar 2021 21:24:56

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[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 (d910329ff6c2fe5f)', Time: '2021-03-14T17:24:42', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '9233b197-071a-48ef-a94e-e216d75f5255'	System	14 Mar 2021 21:24:56
User entered 'No (N)'	System	14 Mar 2021 21:24:56

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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 (d910329ff6c2fe5f)', Time: '2021-03-14T17:24:48', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '9233b197-071a-48ef-a94e-e216d75f5255'	System	14 Mar 2021 21:24:56
User entered 'No (N)'	System	14 Mar 2021 21:24:56

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2021-03-14T17:24:52', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '9233b197-071a-48ef-a94e-e216d75f5255'	System	14 Mar 2021 21:24:56
User entered '14 Mar 2021 17:24:52'	System	14 Mar 2021 21:24:56

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '12 Mar 2021 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '16 Mar 2021 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[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 (d910329ff6c2fe5f)', Time: '2021-03-21T15:34:15', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '261f927f-98d1-49aa-a76e-d68efd56e3dc'	System	21 Mar 2021 19:34:27
User entered 'No (N)'	System	21 Mar 2021 19:34:27

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

Have you been exposed to someone with 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 (d910329ff6c2fe5f)', Time: '2021-03-21T15:34:19', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '261f927f-98d1-49aa-a76e-d68efd56e3dc'	System	21 Mar 2021 19:34:27
User entered 'No (N)'	System	21 Mar 2021 19:34:27

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2021-03-21T15:34:23', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '261f927f-98d1-49aa-a76e-d68efd56e3dc'	System	21 Mar 2021 19:34:27
User entered '21 Mar 2021 15:34:23'	System	21 Mar 2021 19:34:27

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '19 Mar 2021 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '23 Mar 2021 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[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 (d910329ff6c2fe5f)', Time: '2021-03-28T11:14:12', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '8088b15c-53f8-4a45-871e-3cef1e7cfab0'	System	28 Mar 2021 15:14:20
User entered 'No (N)'	System	28 Mar 2021 15:14:20

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

Have you been exposed to someone with 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 (d910329ff6c2fe5f)', Time: '2021-03-28T11:14:14', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '8088b15c-53f8-4a45-871e-3cef1e7cfab0'	System	28 Mar 2021 15:14:20
User entered 'No (N)'	System	28 Mar 2021 15:14:20

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2021-03-28T11:14:18', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '8088b15c-53f8-4a45-871e-3cef1e7cfab0'	System	28 Mar 2021 15:14:20
User entered '28 Mar 2021 11:14:18'	System	28 Mar 2021 15:14:20

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '26 Mar 2021 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '30 Mar 2021 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[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 (d910329ff6c2fe5f)', Time: '2021-04-03T16:20:27', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '184516f8-e726-43c8-8fd7-677e05ae6970'	System	03 Apr 2021 20:20:57
User entered 'Yes (Y)'	System	03 Apr 2021 20:20:57

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

Have you been exposed to someone with 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 (d910329ff6c2fe5f)', Time: '2021-04-03T16:20:33', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '184516f8-e726-43c8-8fd7-677e05ae6970'	System	03 Apr 2021 20:20:57
User entered 'No (N)'	System	03 Apr 2021 20:20:57

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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 (d910329ff6c2fe5f)', Time: '2021-04-03T16:20:37', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '184516f8-e726-43c8-8fd7-677e05ae6970'	System	03 Apr 2021 20:20:57
User entered 'No (N)'	System	03 Apr 2021 20:20:57

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

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 (d910329ff6c2fe5f)', Time: '2021-04-03T16:20:50', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '184516f8-e726-43c8-8fd7-677e05ae6970'	System	03 Apr 2021 20:20:57
User entered 'No (N)'	System	03 Apr 2021 20:20:57

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2021-04-03T16:20:53', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '184516f8-e726-43c8-8fd7-677e05ae6970'	System	03 Apr 2021 20:20:57
User entered '03 Apr 2021 16:20:53'	System	03 Apr 2021 20:20:57

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '02 Apr 2021 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '06 Apr 2021 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[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 (d910329ff6c2fe5f)', Time: '2021-04-13T15:42:04', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '6729df55-cb56-4988-b6c6-6c408c7b9cc1'	System	13 Apr 2021 19:42:14
User entered 'No (N)'	System	13 Apr 2021 19:42:14

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

Have you been exposed to someone with 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 (d910329ff6c2fe5f)', Time: '2021-04-13T15:42:07', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '6729df55-cb56-4988-b6c6-6c408c7b9cc1'	System	13 Apr 2021 19:42:14
User entered 'No (N)'	System	13 Apr 2021 19:42:14

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2021-04-13T15:42:11', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: '6729df55-cb56-4988-b6c6-6c408c7b9cc1'	System	13 Apr 2021 19:42:14
User entered '13 Apr 2021 15:42:11'	System	13 Apr 2021 19:42:14

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '09 Apr 2021 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '13 Apr 2021 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '16 Apr 2021 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '20 Apr 2021 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '23 Apr 2021 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '27 Apr 2021 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '30 Apr 2021 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '04 May 2021 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '07 May 2021 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '11 May 2021 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '14 May 2021 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '18 May 2021 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '21 May 2021 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '25 May 2021 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '28 May 2021 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '01 Jun 2021 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '04 Jun 2021 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '08 Jun 2021 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '11 Jun 2021 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '15 Jun 2021 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '18 Jun 2021 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '22 Jun 2021 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '25 Jun 2021 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '29 Jun 2021 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '02 Jul 2021 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '06 Jul 2021 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '09 Jul 2021 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '13 Jul 2021 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '16 Jul 2021 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '20 Jul 2021 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '23 Jul 2021 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '27 Jul 2021 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '30 Jul 2021 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '03 Aug 2021 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '06 Aug 2021 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '10 Aug 2021 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '13 Aug 2021 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '17 Aug 2021 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '20 Aug 2021 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '24 Aug 2021 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '27 Aug 2021 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '31 Aug 2021 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '03 Sep 2021 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '07 Sep 2021 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '10 Sep 2021 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '14 Sep 2021 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '17 Sep 2021 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '21 Sep 2021 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '24 Sep 2021 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '28 Sep 2021 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '01 Oct 2021 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '05 Oct 2021 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '08 Oct 2021 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '12 Oct 2021 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '15 Oct 2021 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '19 Oct 2021 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '22 Oct 2021 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '26 Oct 2021 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '29 Oct 2021 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '02 Nov 2021 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '05 Nov 2021 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '09 Nov 2021 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '12 Nov 2021 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '16 Nov 2021 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '19 Nov 2021 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '23 Nov 2021 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '26 Nov 2021 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '30 Nov 2021 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '03 Dec 2021 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '07 Dec 2021 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '10 Dec 2021 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '14 Dec 2021 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '17 Dec 2021 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '21 Dec 2021 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '24 Dec 2021 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '28 Dec 2021 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '31 Dec 2021 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '04 Jan 2022 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '07 Jan 2022 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '11 Jan 2022 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '14 Jan 2022 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '18 Jan 2022 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '21 Jan 2022 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '25 Jan 2022 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '28 Jan 2022 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '01 Feb 2022 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '04 Feb 2022 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '08 Feb 2022 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '11 Feb 2022 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '15 Feb 2022 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '18 Feb 2022 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '22 Feb 2022 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '25 Feb 2022 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '01 Mar 2022 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '04 Mar 2022 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '08 Mar 2022 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '11 Mar 2022 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '15 Mar 2022 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '18 Mar 2022 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '22 Mar 2022 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '25 Mar 2022 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '29 Mar 2022 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '01 Apr 2022 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '05 Apr 2022 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '08 Apr 2022 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '12 Apr 2022 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '15 Apr 2022 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '19 Apr 2022 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '22 Apr 2022 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '26 Apr 2022 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '29 Apr 2022 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '03 May 2022 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '06 May 2022 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '10 May 2022 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '13 May 2022 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '17 May 2022 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '20 May 2022 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '24 May 2022 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '27 May 2022 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '31 May 2022 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '03 Jun 2022 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '07 Jun 2022 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '10 Jun 2022 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '14 Jun 2022 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '17 Jun 2022 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '21 Jun 2022 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '24 Jun 2022 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '28 Jun 2022 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '01 Jul 2022 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '05 Jul 2022 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '08 Jul 2022 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '12 Jul 2022 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '15 Jul 2022 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '19 Jul 2022 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '22 Jul 2022 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '26 Jul 2022 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '29 Jul 2022 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '02 Aug 2022 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '05 Aug 2022 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '09 Aug 2022 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '12 Aug 2022 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '16 Aug 2022 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '19 Aug 2022 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '23 Aug 2022 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '26 Aug 2022 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '30 Aug 2022 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '02 Sep 2022 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '06 Sep 2022 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '09 Sep 2022 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '13 Sep 2022 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '16 Sep 2022 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '20 Sep 2022 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '23 Sep 2022 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '27 Sep 2022 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '30 Sep 2022 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '04 Oct 2022 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '07 Oct 2022 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '11 Oct 2022 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '14 Oct 2022 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '18 Oct 2022 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '21 Oct 2022 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '25 Oct 2022 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '28 Oct 2022 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '01 Nov 2022 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '04 Nov 2022 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '08 Nov 2022 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '11 Nov 2022 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '15 Nov 2022 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '18 Nov 2022 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '22 Nov 2022 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '25 Nov 2022 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '29 Nov 2022 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '02 Dec 2022 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '06 Dec 2022 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '09 Dec 2022 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '13 Dec 2022 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '16 Dec 2022 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '20 Dec 2022 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '23 Dec 2022 00:01'	System	20 Nov 2020 13:23:53

US3172469

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:32:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:23:53
Amendment Manager: User entered '27 Dec 2022 23:59'	System	20 Nov 2020 13:23:53

US3172469

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:32:09

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2021-03-09T12:00:20', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'e1d65aaf-f0bc-47ff-b3d4-a1526ebb7356'	System	09 Mar 2021 17:01:17
User entered 'No (N)'	System	09 Mar 2021 17:01:17

US3172469

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:32:09

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:07:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d910329ff6c2fe5f)', Time: '2021-03-09T12:00:28', User OID: 'PatientReportedOutcome (US3172469)', ODM File OID: 'e1d65aaf-f0bc-47ff-b3d4-a1526ebb7356'	System	09 Mar 2021 17:01:17
User entered '09 Mar 2021 12:00:28'	System	09 Mar 2021 17:01:17

US3172469

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:09

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	18 Jan 2021 14:00:48

US3172469

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '14 Jan 2021'	Jessie Downs (b) (4) (b) (4)	18 Jan 2021 14:00:48

US3172469

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:09

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	18 Jan 2021 14:00:48

US3172469

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:09

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Jan 2021 14:00:48

US3172469

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	18 Jan 2021 14:00:54

US3172469

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:09

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:35:36
User entered '1'	System	18 Jan 2021 14:00:54

US3172469

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:09

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:25:20
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	23 Feb 2021 14:43:41
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	18 Feb 2021 14:13:00

US3172469

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:25:20
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	23 Feb 2021 14:43:41
User entered '17 Feb 2021'	Jessie Downs (b) (4) (b) (4)	18 Feb 2021 14:13:00

US3172469

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:09

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:25:20
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	23 Feb 2021 14:43:41
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	18 Feb 2021 14:13:00

US3172469

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:09

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:25:20
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	23 Feb 2021 14:43:41
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Feb 2021 14:13:00

US3172469

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:25:20
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	23 Feb 2021 14:43:41
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	18 Feb 2021 14:13:16

US3172469

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:09

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:25:20
User entered '1'	System	18 Feb 2021 14:13:16

US3172469

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:09

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:11:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:45:30
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	23 Mar 2021 13:43:54

US3172469

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:11:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:45:30
User entered '21 Mar 2021'	Jessie Downs (b) (4) (b) (4)	23 Mar 2021 13:43:54

US3172469

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:09

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:11:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:45:30
User entered 'Contact Not Made (CONTACT NOT MADE)'	Jessie Downs (b) (4) (b) (4)	23 Mar 2021 13:43:54

US3172469

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:09

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:11:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:45:30
User entered 'unable to contact subject. no voicemail set up. emergency contact does not answer.'	Jessie Downs (b) (4) (b) (4)	23 Mar 2021 13:43:54

US3172469

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:11:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:45:30
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	23 Mar 2021 13:43:58

US3172469

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:09

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:11:07
User entered 'I'	System	23 Mar 2021 13:43:58

US3172469

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:09

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:45:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Apr 2021 18:17:49

US3172469

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:45:30
User entered '20 Apr 2021'	(b) (4), (b) (6)	20 Apr 2021 18:17:49

US3172469

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:09

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:45:30
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	20 Apr 2021 18:17:49

US3172469

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:32:09

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:45:30
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 18:17:49

US3172469

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:45:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Apr 2021 18:17:55

US3172469

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:32:09

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Apr 2021 18:17:55

US3172469

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

Form: Visit Date

Generated On: 09 Jun 2021 15:32:09

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 23:00:37

US3172469

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

Form: Visit Date

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '05 Feb 2021'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 23:00:37

US3172469

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

Form: Visit Date

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Clinic (Clinic)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 23:00:37

US3172469

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

Form: Visit Date

Generated On: 09 Jun 2021 15:32:09

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User entered 'UNBLND_DECIDE'	System	05 Feb 2021 23:00:37

US3172469

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

Form: Unblinding

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '06 Jan 2021'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 23:01:34

US3172469

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

Form: Unblinding

Generated On: 09 Jun 2021 15:32:09

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:18:03
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 20:39:59

US3172469

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

Form: Unblinding

Generated On: 09 Jun 2021 15:32:09

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 23:01:34

US3172469

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

Form: Unblinding

Generated On: 09 Jun 2021 15:32:09

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:45:30
User closed query ' Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.	(b) (4), (b) (6)	15 Apr 2021 20:34:19
' (Site from DM). Query ' Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.	Mariete Rendon (b) (4) (b) (4)	12 Apr 2021 14:55:41
' answered with 'Data updated.' (Site from DM). Signature has been broken.	Mariete Rendon (b) (4) (b) (4)	12 Apr 2021 14:54:07
User entered 'Amendment 6 or later (Amendment 6 or later)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	12 Apr 2021 14:54:07
User opened query ' Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.	(b) (4), (b) (6)	09 Apr 2021 22:25:49
' (Site from DM). User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:18:03
User entered empty. WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 20:39:59

US3172469

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

Form: Unblinding

Generated On: 09 Jun 2021 15:32:09

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '05 Feb 2021'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 23:01:34

US3172469

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

Form: Unblinding

Generated On: 09 Jun 2021 15:32:09

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'mRNA-1273 (mRNA-1273)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 23:01:34

US3172469

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

Form: Unblinding

Generated On: 09 Jun 2021 15:32:09

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'mRNA-1273 (mRNA-1273)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 23:01:34

US3172469

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

Form: Unblinding

Generated On: 09 Jun 2021 15:32:09

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'mRNA-1273 (mRNA-1273)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 23:01:34

US3172469

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

Form: Unblinding

Generated On: 09 Jun 2021 15:32:09

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 23:01:34

US3172469

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

Form: Unblinding

Generated On: 09 Jun 2021 15:32:09

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User entered empty.	System	05 Feb 2021 23:01:34

US3172469

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

Form: Unblinding

Generated On: 09 Jun 2021 15:32:09

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User entered empty.	System	05 Feb 2021 23:01:34

US3172469

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:32:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 23:00:52

US3172469

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:32:09

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '05 Feb 2021'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 23:00:52

US3172469

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:32:09

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '10:07'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 23:00:52

US3172469

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User entered '05 Feb 2021 10:07'	System	05 Feb 2021 23:00:52

US3172469

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:32:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 23:01:03

US3172469

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:32:09

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '05 Feb 2021'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 23:01:03

US3172469

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:32:09

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '10:09'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 23:01:03

US3172469

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:47:14
User entered '05 Feb 2021 10:09'	System	05 Feb 2021 23:01:03

US3172469

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:32:09

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:02:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:55:59
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:52:22

US3172469

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:09

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Pain in extremity, LLT: Pain in thigh - version MedDRA\\23.0.	Coder Import (b) (4)	18 Nov 2020 18:47:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	18 Nov 2020 18:47:46
Data point term sent to Coder	System	18 Nov 2020 16:57:51
User entered 'WORSENING OF BASELINE LEFT THIGH PAIN'	Jessie Downs (b) (4)	18 Nov 2020 16:57:29

US3172469

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:09

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:57:29

US3172469

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:09

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:57:29

US3172469

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:09

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:57:29

US3172469

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '14 Nov 2020'	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:57:29

US3172469

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:09

Start time (00:00-23:59)

Audit	User	Time (GMT)
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	18 Nov 2020 16:57:41
User entered empty; reason for change Data Entry Error	Jessie Downs (b) (4)	18 Nov 2020 16:57:41
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	18 Nov 2020 16:57:29
User entered '07:00'	Jessie Downs (b) (4)	18 Nov 2020 16:57:29

US3172469

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:09

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 16:57:41
User entered '14 Nov 2020 07:00'	System	18 Nov 2020 16:57:29

US3172469

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:09

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 21:31:48
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'AE is still ongoing ' (Site from DM).	Jessie Downs (b) (4) (b) (4)	19 Jan 2021 15:30:52
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 10:25:29
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:57:29

US3172469

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:09

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:57:29

US3172469

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:09

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:57:29

US3172469

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:09

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 16:57:29

US3172469

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:09

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:57:29

US3172469

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:09

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please confirm if the AE of worsening of baseline left thigh pain should be upgraded to SAE (to include the hospitalization from the deleted event of worsening of left thigh pain).' (Site from Safety).	(b) (4), (b) (6)	04 Jan 2021 18:06:06
Query 'PV Query: Please confirm if the AE of worsening of baseline left thigh pain should be upgraded to SAE (to include the hospitalization from the deleted event of worsening of left thigh pain).' answered with 'SARs not an AE' (Site from Safety).	Jessie Downs (b) (4) (b) (4)	31 Dec 2020 16:02:13
User opened query 'PV Query: Please confirm if the AE of worsening of baseline left thigh pain should be upgraded to SAE (to include the hospitalization from the deleted event of worsening of left thigh pain).' (Site from Safety).	(b) (4), (b) (6)	31 Dec 2020 14:25:50
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:57:29

US3172469

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:09

Death

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:57:29

US3172469

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:09

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:57:29

US3172469

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:57:29

US3172469

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:09

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:57:29

US3172469

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:09

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:57:29

US3172469

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:09

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:57:29

US3172469

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:09

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:57:29

US3172469

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:57:29

US3172469

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:57:29

US3172469

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:09

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:57:29

US3172469

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:09

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:57:29

US3172469

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:09

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:57:29

US3172469

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:09

Action taken with investigational product

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:57:29

US3172469

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:09

None

Audit	User	Time (GMT)
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	20 Nov 2020 19:37:37
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	18 Nov 2020 16:58:30
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	18 Nov 2020 16:58:21
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	18 Nov 2020 16:57:29
User entered '0'	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:57:29

US3172469

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:09

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0' reason for change: Data Entry Error	Jessie Downs (b) (4)	18 Nov 2020 16:58:30
User entered '1' reason for change: Data Entry Error	Jessie Downs (b) (4)	18 Nov 2020 16:58:21
User entered '0'	Jessie Downs (b) (4)	18 Nov 2020 16:57:29

US3172469

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:09

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '1' reason for change: Data Entry Error	Jessie Downs (b) (4)	20 Nov 2020 19:37:37
User entered '0'	(b) (4) Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:57:29

US3172469

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:09

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:57:29

US3172469

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:09

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:57:29

US3172469

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:09

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:57:29

US3172469

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:09

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	18 Nov 2020 16:57:29

US3172469

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:32:09

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	18 Nov 2020 16:57:29

US3172469

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:09

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 13:04:52
User entered 'USA-US118-2021-mRNA-1273-P301000006'	System	08 Feb 2021 13:04:49
User entered 'New'	(b) (4), (b) (6)	08 Feb 2021 13:04:49

US3172469

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:09

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms male malignant and unspecified, HLT: Prostatic neoplasms malignant, PT: Prostate cancer, LLT: Prostate cancer - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Feb 2021 22:41:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Feb 2021 22:41:50
Data point term sent to Coder	System	05 Feb 2021 22:40:49
User entered 'prostate cancer'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:40:21

US3172469

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:09

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:40:21

US3172469

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:09

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:40:21

US3172469

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:09

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

Audit	User	Time (GMT)
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:40:21

US3172469

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: The start dates for the events, prostate cancer and bone metastasis, are recorded as 11 Dec 2020. Per case narrative, subject was hospitalized on 14 Nov 2020 and was diagnosed with prostate cancer and bone metastasis during that time. Please provide rationale as to why the event date is "confirmed as entered".' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 21:32:23
User closed query 'PV Query: The start dates for the events, prostate cancer and bone metastasis, are recorded as 11 Dec 2020. Per case narrative, subject was hospitalized on 14 Nov 2020 and was diagnosed with prostate cancer and bone metastasis during that time. Please confirm start date of event.' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 21:32:23
Query 'PV Query: The start dates for the events, prostate cancer and bone metastasis, are recorded as 11 Dec 2020. Per case narrative, subject was hospitalized on 14 Nov 2020 and was diagnosed with prostate cancer and bone metastasis during that time. Please confirm start date of event.' answered with 'Date confirmed as entered.' (Site from Safety).	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 21:38:12
User opened query 'PV Query: The start dates for the events, prostate cancer and bone metastasis, are recorded as 11 Dec 2020. Per case narrative, subject was hospitalized on 14 Nov 2020 and was diagnosed with prostate cancer and bone metastasis during that time. Please confirm start date of event.' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 20:10:11
User closed query 'PV Query: The start dates for the events, prostate cancer and bone metastasis, are recorded as 11 Dec 2020. Per case narrative, subject was hospitalized on 14 Nov 2020 and was diagnosed with prostate cancer and bone metastasis during that time. Please confirm start date of event.' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 17:28:14
Query 'PV Query: The start dates for the events, prostate cancer and bone metastasis, are recorded as 11 Dec 2020. Per case narrative, subject was hospitalized on 14 Nov 2020 and was diagnosed with prostate cancer and bone metastasis during that time. Please confirm start date of event.' answered with 'date confirmed as entered.' (Site from Safety).	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 20:43:39

US3172469

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: The start dates for the events, prostate cancer and bone metastasis, are recorded as 11 Dec 2020. Per case narrative, subject was hospitalized on 14 Nov 2020 and was diagnosed with prostate cancer and bone metastasis during that time. Please confirm start date of event.' (Site from Safety). User entered '11 Dec 2020'	(b) (4), (b) (6) [REDACTED]	12 Feb 2021 20:57:46
	Jessie Downs (b) (4) [REDACTED]	05 Feb 2021 22:40:21

US3172469

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:09

Start time (00:00-23:59)

Audit	User	Time (GMT)
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	05 Feb 2021 22:40:36
User entered empty; reason for change Data Entry Error	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:40:36
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	05 Feb 2021 22:40:21
User entered '08:33'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:40:21

US3172469

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:09

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Feb 2021 22:40:36
User entered '11 Dec 2020 08:33'	System	05 Feb 2021 22:40:21

US3172469

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:09

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:40:21

US3172469

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:09

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide event end dates, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 21:33:00
User closed query 'PV Query: Please provide event end dates, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 21:33:00
Query 'PV Query: Please provide event end dates, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' answered with 'pending ' (Site from Safety).	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 21:38:31
User opened query 'PV Query: Please provide event end dates, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 20:14:08
User closed query 'PV Query: Please provide event end dates, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 17:28:18

US3172469

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:09

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'PV Query: Please provide event end dates, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' answered with 'pending medical records ' (Site from Safety).	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 20:42:12
User opened query 'PV Query: Please provide event end dates, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 21:00:39
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:40:21

US3172469

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:09

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:40:21

US3172469

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:09

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Feb 2021 22:40:21

US3172469

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:09

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 4 (Grade 4)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:40:21

US3172469

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:09

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
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).	System	05 Feb 2021 22:55:02
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	05 Feb 2021 22:40:21
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:40:21

US3172469

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:09

Death

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:40:21

US3172469

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:09

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:40:21

US3172469

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
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).	System	05 Feb 2021 22:56:21
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	05 Feb 2021 22:56:21
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	05 Feb 2021 22:55:02
User entered '1' reason for change: Data Entry Error	Jessie Downs (b) (4)	05 Feb 2021 22:55:02
User entered '0'	(b) (4) Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:40:21

US3172469

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:09

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '14 Nov 2020' reason for change: Data Entry Error	Jessie Downs (b) (4)	05 Feb 2021 22:56:13
User entered empty.	Jessie Downs (b) (4)	05 Feb 2021 22:40:21

US3172469

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:09

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '15 Jan 2021' reason for change: Data Entry Error	Jessie Downs (b) (4)	05 Feb 2021 22:56:13
User entered empty.	Jessie Downs (b) (4)	05 Feb 2021 22:40:21

US3172469

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:09

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4)	05 Feb 2021 22:56:21
User entered empty.	Jessie Downs (b) (4)	05 Feb 2021 22:40:21

US3172469

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:09

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:40:21

US3172469

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:40:21

US3172469

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:40:21

US3172469

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:09

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:40:21

US3172469

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:09

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:40:21

US3172469

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:09

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:40:21

US3172469

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:09

Action taken with investigational product

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:40:21

US3172469

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:09

None

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:40:21

US3172469

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:09

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:40:21

US3172469

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:09

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:40:21

US3172469

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:09

[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide final event outcomes, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 21:33:19
User closed query 'PV Query: Please provide final event outcomes, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 21:33:19
Query 'PV Query: Please provide final event outcomes, when available. Please keep query open until resolution is achieved.' answered with 'pending' (Site from Safety).	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 21:38:46
User opened query 'PV Query: Please provide final event outcomes, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 20:13:27
User closed query 'PV Query: Please provide final event outcomes, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 17:28:24
Query 'PV Query: Please provide final event outcomes, when available. Please keep query open until resolution is achieved.' answered with 'pending medical records ' (Site from Safety).	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 20:42:24
User opened query 'PV Query: Please provide final event outcomes, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 21:00:03
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:40:21

US3172469

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:09

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:40:21

US3172469

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:09

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 21:33:43
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 21:33:43
User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with prostate cancer.' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 21:33:36
User closed query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with prostate cancer.' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 21:33:36
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 21:33:29
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 21:33:29
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'pending' (Site from Safety).	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 21:39:29

US3172469

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:09

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with prostate cancer.' answered with 'pending' (Site from Safety).	Jessie Downs (b) (4)	26 Feb 2021 21:39:15
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'pending' (Site from Safety).	Jessie Downs (b) (4)	26 Feb 2021 21:39:01
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 20:13:08
User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with prostate cancer.' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 20:12:50
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 20:12:37
Query 'PV Query: Please confirm if bone metastasis is a result of prostate cancer and can be removed as a separate event.' canceled (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 20:10:50
User opened query 'PV Query: Please confirm if bone metastasis is a result of prostate cancer and can be removed as a separate event.' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 20:10:31
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 17:28:58

US3172469

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:09

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 17:28:39
User closed query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with prostate cancer.' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 17:28:33
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 17:28:28
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' answered with 'pending medical records ' (Site from Safety).	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 20:43:19
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'pending medical records ' (Site from Safety).	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 20:43:06
Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with prostate cancer.' answered with 'pending medical records ' (Site from Safety).	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 20:42:54
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'pending medical records ' (Site from Safety).	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 20:42:37

US3172469

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:09

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 21:01:07
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 20:59:52
User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with prostate cancer.' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 20:59:40
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 20:59:27
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	05 Feb 2021 22:54:32
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	05 Feb 2021 22:54:32
User entered 'patient came in for decision visit open - label. he got the MRNA vaccine after unblinded. no need for vaccination today. he was hospitalized from 11/14/2020 to 01/15/2021 due to severe and intractable left thigh pain radiating to left knee. per discharge records brought by subject today, he was diagnosed with prostate cancer with bone metastasis. he is currently on Lupron and bicalutamide for prostate cancer and oxycodone, gabapentin and diclofenac topical for left thigh and knee pain. More information will be provided upon medical records from hospitalization are received/ reviewed.' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:54:32

US3172469

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:09

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	05 Feb 2021 22:40:21
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:40:21

US3172469

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:09

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	05 Feb 2021 22:40:21

US3172469

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:09

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	05 Feb 2021 22:40:21

US3172469

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:32:09

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Feb 2021 22:56:21

US3172469

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:09

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 13:05:31
User entered 'USA-US118-2021-mRNA-1273-P301000006'	(b) (4), (b) (6)	08 Feb 2021 13:05:28

US3172469

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:09

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please confirm if bone metastasis is a result of prostate cancer and can be removed as a separate event. Please provide rationale for retaining as separate event.' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 21:34:45
User closed query 'PV Query: Please confirm if bone metastasis is a result of prostate cancer and can be removed as a separate event.' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 21:34:45
Query 'PV Query: Please confirm if bone metastasis is a result of prostate cancer and can be removed as a separate event.' answered with 'Data confirmed as entered.' (Site from Safety).	Jessie Downs (b) (4)	26 Feb 2021 21:40:27
User opened query 'PV Query: Please confirm if bone metastasis is a result of prostate cancer and can be removed as a separate event.' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 20:58:16
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLG: Metastases, HLT: Metastases to specified sites, PT: Metastases to bone, LLT: Bone metastases - version MedDRA\\23.0.	Coder Import (b) (4)	07 Feb 2021 13:34:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	07 Feb 2021 13:34:43
Data point term sent to Coder	System	05 Feb 2021 22:43:00
User entered 'bone metastasis manifested by intractable left thigh pain radiation to left knee'	Jessie Downs (b) (4)	05 Feb 2021 22:42:17

US3172469

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:09

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:42:17

US3172469

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:09

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4)	05 Feb 2021 22:42:44
User entered 'Yes (Y)'	Jessie Downs (b) (4)	05 Feb 2021 22:42:17

US3172469

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:09

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:42:17

US3172469

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: The start dates for the events, prostate cancer and bone metastasis, are recorded as 11 Dec 2020. Per case narrative, subject was hospitalized on 14 Nov 2020 and was diagnosed with prostate cancer and bone metastasis during that time. Please provide rationale as to why the event date is "confirmed as entered".' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 21:31:56
User closed query 'PV Query: The start dates for the events, prostate cancer and bone metastasis, are recorded as 11 Dec 2020. Per case narrative, subject was hospitalized on 14 Nov 2020 and was diagnosed with prostate cancer and bone metastasis during that time. Please confirm start date of event.' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 21:31:56
Query 'PV Query: The start dates for the events, prostate cancer and bone metastasis, are recorded as 11 Dec 2020. Per case narrative, subject was hospitalized on 14 Nov 2020 and was diagnosed with prostate cancer and bone metastasis during that time. Please confirm start date of event.' answered with 'Date confirmed as entered.' (Site from Safety).	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 21:40:49
User opened query 'PV Query: The start dates for the events, prostate cancer and bone metastasis, are recorded as 11 Dec 2020. Per case narrative, subject was hospitalized on 14 Nov 2020 and was diagnosed with prostate cancer and bone metastasis during that time. Please confirm start date of event.' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 20:11:59
User entered '11 Dec 2020'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:42:17

US3172469

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:09

Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:42:17

US3172469

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:09

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Feb 2021 22:42:17

US3172469

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:09

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:42:17

US3172469

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:09

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide event end dates, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 21:30:05
User closed query 'PV Query: Please provide event end dates, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 21:30:05
Query 'PV Query: Please provide event end dates, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' answered with 'pending' (Site from Safety).	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 21:41:03
User opened query 'PV Query: Please provide event end dates, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 20:13:54
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:42:17

US3172469

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:09

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:42:17

US3172469

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:09

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Feb 2021 22:42:17

US3172469

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:09

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 4 (Grade 4)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:42:17

US3172469

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:09

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
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).	System	05 Feb 2021 22:57:04
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	05 Feb 2021 22:42:17
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:42:17

US3172469

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:09

Death

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:42:17

US3172469

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:09

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:42:17

US3172469

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '1' reason for change: Data Entry Error	Jessie Downs (b) (4)	05 Feb 2021 22:57:04
User entered '0'	(b) (4) Jessie Downs (b) (4)	05 Feb 2021 22:42:17

US3172469

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:09

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '14 Nov 2020' reason for change: Data Entry Error	Jessie Downs (b) (4)	05 Feb 2021 22:57:04
User entered empty.	Jessie Downs (b) (4)	05 Feb 2021 22:42:17

US3172469

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:09

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '15 Jan 2021' reason for change: Data Entry Error	Jessie Downs (b) (4)	05 Feb 2021 22:57:04
User entered empty.	Jessie Downs (b) (4)	05 Feb 2021 22:42:17

US3172469

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:09

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4)	05 Feb 2021 22:57:04
User entered empty.	Jessie Downs (b) (4)	05 Feb 2021 22:42:17

US3172469

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:09

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:42:17

US3172469

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:42:17

US3172469

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:42:17

US3172469

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:09

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:42:17

US3172469

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:09

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:42:17

US3172469

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:09

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:42:17

US3172469

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:09

Action taken with investigational product

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:42:17

US3172469

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:09

None

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:42:17

US3172469

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:09

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:42:17

US3172469

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:09

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:42:17

US3172469

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:09

[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide final event outcomes, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 21:29:08
User closed query 'PV Query: Please provide final event outcomes, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 21:29:08
Query 'PV Query: Please provide final event outcomes, when available. Please keep query open until resolution is achieved.' answered with 'pending' (Site from Safety).	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 21:41:18
User opened query 'PV Query: Please provide final event outcomes, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 20:13:36
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:42:17

US3172469

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:09

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:42:17

US3172469

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:09

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	05 Feb 2021 22:57:04
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	05 Feb 2021 22:57:04
User entered 'patient came in for decision visit open - label. he got the MRNA vaccine after unblinded. no need for vaccination today. he was hospitalized from 11/14/2020 to 01/15/2021 due to severe and intractable left thigh pain radiating to left knee. per discharge records brought by subject today, he was diagnosed with prostate cancer with bone metastasis. he is currently on Lupron and bicalutamide for prostate cancer and oxycodone, gabapentin and diclofenac topical for left thigh and knee pain. More information will be provided upon medical records from hospitalization are received/ reviewed.' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:57:04
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	05 Feb 2021 22:42:17
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:42:17

US3172469

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:09

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	05 Feb 2021 22:42:17

US3172469

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:09

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	05 Feb 2021 22:42:17

US3172469

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:32:09

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Feb 2021 22:57:04

US3172469

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:09

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 16:27:47
User entered 'USA-US118-2021-mRNA-1273-P301000016'	System	14 Apr 2021 16:27:25
User entered 'New'	(b) (4), (b) (6)	14 Apr 2021 16:27:25

US3172469

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:09

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Pain in extremity, LLT: Pain in thigh - version MedDRA\\23.0.	Coder Import (b) (4)	15 Apr 2021 11:06:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	15 Apr 2021 11:06:48
Data point term sent to Coder	System	13 Apr 2021 20:42:50
User entered 'left thigh pain worsening'	Jessie Downs (b) (4)	13 Apr 2021 20:42:11

US3172469

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:09

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 20:42:11

US3172469

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:09

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 20:42:11

US3172469

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:09

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 20:42:11

US3172469

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '22 Mar 2021'	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 20:42:11

US3172469

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:09

Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 20:42:11

US3172469

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:09

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 20:42:11

US3172469

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:09

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 20:42:11

US3172469

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:09

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '12 Apr 2021'	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 20:42:11

US3172469

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:09

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 20:42:11

US3172469

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:09

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 20:42:11

US3172469

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:09

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 3/Severe (Grade 3/Severe)'	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 20:42:11

US3172469

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:09

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 20:42:11

US3172469

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:09

Death

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 20:42:11

US3172469

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:09

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 20:42:11

US3172469

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
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).	System	13 Apr 2021 20:44:04
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	13 Apr 2021 20:44:04
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	13 Apr 2021 20:42:11
User entered '1'	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 20:42:11

US3172469

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:09

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '22 Mar 2021' reason for change: Data Entry Error	Jessie Downs (b) (4)	13 Apr 2021 20:44:04
User entered empty.	Jessie Downs (b) (4)	13 Apr 2021 20:42:11

US3172469

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:09

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '12 Apr 2021' reason for change: Data Entry Error	Jessie Downs (b) (4)	13 Apr 2021 20:44:04
User entered empty.	Jessie Downs (b) (4)	13 Apr 2021 20:42:11

US3172469

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:09

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 20:42:11

US3172469

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:09

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 20:42:11

US3172469

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 20:42:11

US3172469

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 20:42:11

US3172469

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:09

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 20:42:11

US3172469

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:09

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 20:42:11

US3172469

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:09

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 20:42:11

US3172469

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:09

Action taken with investigational product

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 20:42:11

US3172469

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:09

None

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 20:42:11

US3172469

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:09

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1'	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 20:42:11

US3172469

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:09

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '1'	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 20:42:11

US3172469

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:09

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 20:42:11

US3172469

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:09

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	13 Apr 2021 20:42:11

US3172469

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:09

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Was there a triggering reason to this episode of pain in left thigh? ' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 15:58:35
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 15:58:26
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 15:58:15
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 15:58:06
User entered 'subject called is reporting reoccurrence of left thigh pain worsening episode being admitted to Jackson Memorial Hospital where he has had a surgical procedure (he doesn't know) and was discharged on 12Apr2021. Additional information to be provided when medical records are received.' reason for change: Data Entry Error	Jessie Downs (b) (4)	13 Apr 2021 20:47:29
User entered empty.	Jessie Downs (b) (4)	13 Apr 2021 20:42:11

US3172469

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:09

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 20:42:11

US3172469

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:09

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 20:42:11

US3172469

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:32:09

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	13 Apr 2021 20:42:11

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:32:09

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:02:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User closed query 'Per DM CLR: Per Diary Dose 1 Day 1, 3, 5 Pain at Injection Site; Day 5 Underarm Gland Swelling or Tenderness; Day 1-3 Headache (General) = Any use of prescription pain reliever or prevents daily activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM). Query 'Per DM CLR: Per Diary Dose 1 Day 1, 3, 5 Pain at Injection Site; Day 5 Underarm Gland Swelling or Tenderness; Day 1-3 Headache (General) = Any use of prescription pain reliever or prevents daily activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' answered with 'Source verified with Safety Call 8 that subject entered data on diary in error for Day 1, 3 and 5.' (Site from DM).	(b) (4), (b) (6) Jessie Downs (b) (4) (b) (4)	12 Feb 2021 21:29:33 26 Jan 2021 18:41:01
User opened query 'Per DM CLR: Per Diary Dose 1 Day 1, 3, 5 Pain at Injection Site; Day 5 Underarm Gland Swelling or Tenderness; Day 1-3 Headache (General) = Any use of prescription pain reliever or prevents daily activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	23 Jan 2021 11:42:02
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:54:20
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	22 Oct 2020 12:52:32

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:32:09

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 11:21:56
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 Nov 2020 11:21:56
Data point term sent to Coder	System	18 Nov 2020 16:55:50
User entered 'IBUPROFEN'	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:55:19

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:32:09

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:55:19

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:32:09

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Indication is Left Thigh Pain however, corresponding AE is not recorded with Other Action Taken= Concomitant Medication. Please update Other Action Taken of the corresponding AE or provide explanation '(Site from DM).	(b) (4), (b) (6)	28 Apr 2021 05:06:41
Query 'Per DM CLR: Indication is Left Thigh Pain however, corresponding AE is not recorded with Other Action Taken= Concomitant Medication. Please update Other Action Taken of the corresponding AE or provide explanation ' answered with 'Other Action Taken is recorded with concomitant medication.' (Site from DM).	Jessie Downs (b) (4) (b) (4)	26 Apr 2021 19:55:06
User opened query 'Per DM CLR: Indication is Left Thigh Pain however, corresponding AE is not recorded with Other Action Taken= Concomitant Medication. Please update Other Action Taken of the corresponding AE or provide explanation '(Site from DM).	(b) (4), (b) (6)	07 Apr 2021 08:04:57
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'LEFT THIGH PAIN'	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:55:19

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:32:09

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '800'	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:55:19

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:32:09

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:55:19

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:32:09

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:55:19

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:32:09

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'once daily (QD)'	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:55:19

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:32:09

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:55:19

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:32:09

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:55:19

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:32:09

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:55:19

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:32:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '14 Nov 2020'	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:55:19

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:32:09

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '0'	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:55:19

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:32:09

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:55:19

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:32:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:55:19

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:32:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	18 Nov 2020 16:55:19

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:32:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Nov 2020 16:55:19

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:32:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Nov 2020 16:55:19

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:32:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Nov 2020 16:55:19

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:32:09

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Jan 2021 20:54:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Jan 2021 20:54:43
Data point term sent to Coder	System	11 Jan 2021 20:54:04
User entered 'albuterol'	Jessie Downs (b) (4) (b) (4)	11 Jan 2021 20:53:10

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:32:09

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	11 Jan 2021 20:53:10

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:32:09

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'mild asthma'	Jessie Downs (b) (4) (b) (4)	11 Jan 2021 20:53:10

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:32:09

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '90'	Jessie Downs (b) (4) (b) (4)	11 Jan 2021 20:53:10

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:32:09

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Other (OTHER)'	Jessie Downs (b) (4) (b) (4)	11 Jan 2021 20:53:10

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:32:09

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'mcg'	Jessie Downs (b) (4) (b) (4)	11 Jan 2021 20:53:10

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:32:09

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'other (OTHER)'	Jessie Downs (b) (4) (b) (4)	11 Jan 2021 20:53:10

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:32:09

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '4-6 hours, prn'	Jessie Downs (b) (4) (b) (4)	11 Jan 2021 20:53:10

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:32:09

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Jessie Downs (b) (4) (b) (4)	11 Jan 2021 20:53:10

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:32:09

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	11 Jan 2021 20:53:10

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:32:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'un UNK 1999'	Jessie Downs (b) (4) (b) (4)	11 Jan 2021 20:53:10

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:32:09

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '0'	Jessie Downs (b) (4) (b) (4)	11 Jan 2021 20:53:10

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:32:09

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	11 Jan 2021 20:53:10

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:32:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	11 Jan 2021 20:53:10

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:32:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	11 Jan 2021 20:53:10

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:32:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Jan 2021 20:53:10

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:32:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Jan 2021 20:53:10

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:32:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Jan 2021 20:53:10

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:32:09

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: ANTIINFLAMMATORY PREPARATIONS, NON-STEROIDS FOR TOPICAL USE, PRODUCT: DICLOFENAC - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	06 Feb 2021 19:25:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	06 Feb 2021 19:25:47
Data point term sent to Coder	System	05 Feb 2021 22:45:04
User entered 'diclofenac'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:44:05

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:32:09

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:44:05

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:32:09

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'knee pain'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:44:05

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:32:09

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '1'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:44:05

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:32:09

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Other (OTHER)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:44:05

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:32:09

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'percent'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:44:05

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:32:09

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'four times daily (QID)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:44:05

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:32:09

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:44:05

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:32:09

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Topical (TOPICAL)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:44:05

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:32:09

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:44:05

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:32:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '21 Jan 2021'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:44:05

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:32:09

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '0'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:44:05

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:32:09

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:44:05

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:32:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:44:05

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:32:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:44:05

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:32:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '4'	System	05 Feb 2021 22:44:05

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:32:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Feb 2021 22:44:05

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:32:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Feb 2021 22:44:05

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:32:09

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: ENDOCRINE THERAPY, ATC: HORMONES AND RELATED AGENTS, ATC: GONADOTROPIN RELEASING HORMONE ANALOGUES, PRODUCT: LEUPRORELIN ACETATE, PRODUCTSYNONYM: LUPRON DEPOT - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Feb 2021 22:45:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Feb 2021 22:45:57
Data point term sent to Coder	System	05 Feb 2021 22:45:05
User entered 'lupron depot'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:45:01

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:32:09

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:45:01

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:32:09

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'prostate cancer'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:45:01

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:32:09

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '22.5'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:45:01

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:32:09

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:45:01

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:32:09

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:45:01

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:32:09

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'other (OTHER)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:45:01

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:32:09

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'every 3 months'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:45:01

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:32:09

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Intramuscular (INTRAMUSCULAR)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:45:01

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:32:09

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:45:01

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:32:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '22 Jan 2021'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:45:01

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:32:09

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '0'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:45:01

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:32:09

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:45:01

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:32:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:45:01

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:32:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:45:01

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:32:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Feb 2021 22:45:01

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:32:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Feb 2021 22:45:01

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:32:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Feb 2021 22:45:01

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:32:09

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE HYDROCHLORIDE, PRODUCTSYNONYM: OXYCODONE HCL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Mar 2021 19:56:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Mar 2021 19:56:53
Data point term sent to Coder Coding entries removed.	System Jessie Downs (b) (4) (b) (4)	11 Mar 2021 19:56:28 11 Mar 2021 19:55:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE HYDROCHLORIDE, PRODUCTSYNONYM: OXYCODONE HCL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Feb 2021 22:46:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Feb 2021 22:46:49
Data point term sent to Coder User entered 'oxycodone hcl'	System Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:46:05 05 Feb 2021 22:45:43

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:32:09

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:45:43

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:32:09

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:18:03
User closed query 'Per CDM: Thank you for your response, however, please record your response as a part of indication rather than the query.' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 13:16:10
Query 'Per CDM: Thank you for your response, however, please record your response as a part of indication rather than the query.' answered with 'Data was updated.' (Site from DM).	Jessie Downs (b) (4) (b) (4)	11 Mar 2021 19:55:47
Signature has been broken.	Jessie Downs (b) (4) (b) (4)	11 Mar 2021 19:55:29
User entered 'LEFT THIGH PAIN' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	11 Mar 2021 19:55:29
User opened query 'Per CDM: Thank you for your response, however, please record your response as a part of indication rather than the query.' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 16:36:16
User closed query 'Per DM CLR: Please update the condition to include the type and/or location of Pain (knee, arms, legs, Generalized, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 16:36:16
Query 'Per DM CLR: Please update the condition to include the type and/or location of Pain (knee, arms, legs, Generalized, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match ' answered with 'generalized' (Site from DM).	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 21:36:43
User opened query 'Per DM CLR: Please update the condition to include the type and/or location of Pain (knee, arms, legs, Generalized, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match ' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 17:52:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'pain'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:45:43

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:32:09

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '10'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:45:43

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:32:09

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:45:43

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:32:09

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:45:43

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:32:09

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'three times daily (TID)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:45:43

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:32:09

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:45:43

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:32:09

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:45:43

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:32:09

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:45:43

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:32:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '18 Dec 2020'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:45:43

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:32:09

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '0'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:45:43

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:32:09

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:45:43

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:32:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:45:43

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:32:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:45:43

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:32:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	05 Feb 2021 22:45:43

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:32:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Feb 2021 22:45:43

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:32:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Feb 2021 22:45:43

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:32:09

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Mar 2021 12:01:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Mar 2021 12:01:59
Data point term sent to Coder Coding entries removed.	System Jessie Downs (b) (4) (b) (4)	11 Mar 2021 19:56:28 11 Mar 2021 19:56:08
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Feb 2021 22:47:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Feb 2021 22:47:50
Data point term sent to Coder User entered 'gabapentin'	System Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:47:06 05 Feb 2021 22:46:22

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:32:09

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:46:22

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:32:09

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per CDM CR: 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 as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Apr 2021 05:06:31
Query 'Per CDM CR: 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 as appropriate. ' answered with 'Subject takes this medication for AE #4.' (Site from DM).	Jessie Downs (b) (4) (b) (4)	26 Apr 2021 19:58:27
User opened query 'Per CDM CR: 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 as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 09:38:25
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:18:03
User closed query ' Per CDM: Thank you for your response, however, please record your response as a part of indication rather than the query.' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 13:16:21
Query ' Per CDM: Thank you for your response, however, please record your response as a part of indication rather than the query.' answered with 'Data was updated.' (Site from DM).	Jessie Downs (b) (4) (b) (4)	11 Mar 2021 19:56:22
Signature has been broken.	Jessie Downs (b) (4) (b) (4)	11 Mar 2021 19:56:08
User entered 'BILATERAL LEFT EXTREMITIES NUMBNESS' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	11 Mar 2021 19:56:08
User opened query ' Per CDM: Thank you for your response, however, please record your response as a part of indication rather than the query.' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 16:36:33

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:32:09

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please specify the location and/or type of Numbness. Review and update Indication and ensure to reconcile with AE entries so there is an appropriate match ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 16:36:33
Query 'Per DM CLR: Please specify the location and/or type of Numbness. Review and update Indication and ensure to reconcile with AE entries so there is an appropriate match ' answered with 'generalized ' (Site from DM).	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 21:37:09
User opened query 'Per DM CLR: Please specify the location and/or type of Numbness. Review and update Indication and ensure to reconcile with AE entries so there is an appropriate match ' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 17:54:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'numbness'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:46:22

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:32:09

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '600'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:46:22

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:32:09

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:46:22

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:32:09

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:46:22

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:32:09

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'three times daily (TID)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:46:22

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:32:09

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:46:22

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:32:09

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:46:22

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:32:09

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:46:22

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:32:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '18 Dec 2020'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:46:22

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:32:09

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '0'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:46:22

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:32:09

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:46:22

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:32:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:46:22

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:32:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:46:22

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:32:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	05 Feb 2021 22:46:22

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:32:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Feb 2021 22:46:22

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:32:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Feb 2021 22:46:22

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:32:09

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: ENDOCRINE THERAPY, ATC: HORMONE ANTAGONISTS AND RELATED AGENTS, ATC: ANTI-ANDROGENS, PRODUCT: BICALUTAMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Feb 2021 09:05:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Feb 2021 09:05:57
Data point term sent to Coder	System	05 Feb 2021 22:59:18
User entered 'bicalutamide'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:58:24

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:32:09

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:58:24

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:32:09

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'prostate cancer'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:58:24

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:32:09

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '50'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:58:24

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:32:09

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:58:24

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:32:09

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:58:24

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:32:09

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'other (OTHER)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:58:24

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:32:09

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'bedtime'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:58:24

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:32:09

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:58:24

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:32:09

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:58:24

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:32:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '18 Dec 2020'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:58:24

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:32:09

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '0'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:58:24

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:32:09

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:58:24

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:32:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:58:24

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:32:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	05 Feb 2021 22:58:24

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:32:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Feb 2021 22:58:24

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:32:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Feb 2021 22:58:24

US3172469

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:32:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Feb 2021 22:58:24

US3172469

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:32:09

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:45:30
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4)	01 Apr 2021 19:57:45
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4)	31 Mar 2021 14:07:17
	(b) (4)	
Signature has been broken.	Jessie Downs (b) (4)	31 Mar 2021 14:06:57
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4)	31 Mar 2021 14:06:57
	(b) (4)	
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:52:37
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4)	20 Nov 2020 19:38:09
	(b) (4)	
User entered 'No (N)'	Mariete Rendon (b) (4)	22 Oct 2020 12:52:27
	(b) (4)	

US3172469

Folder: SAE USA-US118-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:09

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 19:11:50
User entered 'USA-US118-2020-MRNA-1273-P301000012'	System	11 Dec 2020 19:11:04

US3172469

Folder: SAE USA-US118-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:09

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 19:11:50
User entered 'Yes (Y)'	System	11 Dec 2020 19:11:04

US3172469

Folder: SAE USA-US118-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:09

Death

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 19:11:50
User entered 'No (N)'	System	11 Dec 2020 19:11:04

US3172469

Folder: SAE USA-US118-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:09

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 19:11:50
User entered 'No (N)'	System	11 Dec 2020 19:11:04

US3172469

Folder: SAE USA-US118-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 19:11:50
User entered 'Yes (Y)'	System	11 Dec 2020 19:11:04

US3172469

Folder: SAE USA-US118-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 19:11:50
User entered 'No (N)'	System	11 Dec 2020 19:11:04

US3172469

Folder: SAE USA-US118-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 19:11:50
User entered 'No (N)'	System	11 Dec 2020 19:11:04

US3172469

Folder: SAE USA-US118-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:09

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 19:11:50
User entered 'No (N)'	System	11 Dec 2020 19:11:04

US3172469

Folder: SAE USA-US118-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:09

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 19:11:50
User entered 'Mark'	System	11 Dec 2020 19:11:04

US3172469

Folder: SAE USA-US118-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:09

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 19:11:50
User entered 'Kutner'	System	11 Dec 2020 19:11:04

US3172469

Folder: SAE USA-US118-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:09

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 19:11:50
User entered 'FL'	System	11 Dec 2020 19:11:04

US3172469

Folder: SAE USA-US118-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:09

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'US'	System	11 Dec 2020 19:12:13

US3172469

Folder: SAE USA-US118-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '1'	System	11 Dec 2020 19:12:13

US3172469

Folder: SAE USA-US118-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:09

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 19:11:50
User entered 'USA-US118-2020-MRNA-1273-P301000012'	System	11 Dec 2020 19:11:04

US3172469

Folder: SAE USA-US118-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:09

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 19:11:50
User entered 'Yes (Y)'	System	11 Dec 2020 19:11:04

US3172469

Folder: SAE USA-US118-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:09

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 19:11:50
User entered 'No (N)'	System	11 Dec 2020 19:11:04

US3172469

Folder: SAE USA-US118-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:09

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 19:11:50
User entered 'No (N)'	System	11 Dec 2020 19:11:04

US3172469

Folder: SAE USA-US118-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 19:11:50
User entered 'Yes (Y)'	System	11 Dec 2020 19:11:04

US3172469

Folder: SAE USA-US118-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 19:11:50
User entered 'No (N)'	System	11 Dec 2020 19:11:04

US3172469

Folder: SAE USA-US118-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 19:11:50
User entered 'No (N)'	System	11 Dec 2020 19:11:04

US3172469

Folder: SAE USA-US118-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:09

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 19:11:50
User entered 'No (N)'	System	11 Dec 2020 19:11:04

US3172469

Folder: SAE USA-US118-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:09

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 19:11:50
User entered 'Mark'	System	11 Dec 2020 19:11:04

US3172469

Folder: SAE USA-US118-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:09

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 19:11:50
User entered 'Kutner'	System	11 Dec 2020 19:11:04

US3172469

Folder: SAE USA-US118-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:09

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 19:11:50
User entered 'FL'	System	11 Dec 2020 19:11:04

US3172469

Folder: SAE USA-US118-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:09

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'US'	System	11 Dec 2020 19:12:13

US3172469

Folder: SAE USA-US118-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '1'	System	11 Dec 2020 19:12:13

US3172469

Folder: SAE USA-US118-2020-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:32:09

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '11/Dec/2020 14:12'	System	11 Dec 2020 19:12:13

US3172469

Folder: SAE USA-US118-2020-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:32:09

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.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
Reviewed for Safety.	(b) (4), (b) (6)	11 Dec 2020 19:12:24
User entered '1'	(b) (4), (b) (6)	11 Dec 2020 19:12:13

US3172469

Folder: SAE USA-US118-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:09

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 13:05:45
User entered 'USA-US118-2021-MRNA-1273-P301000006'	System	08 Feb 2021 13:04:49

US3172469

Folder: SAE USA-US118-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:09

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 13:05:45
User entered 'Yes (Y)'	System	08 Feb 2021 13:04:49

US3172469

Folder: SAE USA-US118-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:09

Death

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 13:05:45
User entered 'No (N)'	System	08 Feb 2021 13:04:49

US3172469

Folder: SAE USA-US118-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:09

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 13:05:45
User entered 'No (N)'	System	08 Feb 2021 13:04:49

US3172469

Folder: SAE USA-US118-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 13:05:45
User entered 'Yes (Y)'	System	08 Feb 2021 13:04:49

US3172469

Folder: SAE USA-US118-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 13:05:45
User entered 'No (N)'	System	08 Feb 2021 13:04:49

US3172469

Folder: SAE USA-US118-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 13:05:45
User entered 'No (N)'	System	08 Feb 2021 13:04:49

US3172469

Folder: SAE USA-US118-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:09

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 13:05:45
User entered 'No (N)'	System	08 Feb 2021 13:04:49

US3172469

Folder: SAE USA-US118-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:09

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 13:05:45
User entered 'Mark'	System	08 Feb 2021 13:04:49

US3172469

Folder: SAE USA-US118-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:09

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 13:05:45
User entered 'Kutner'	System	08 Feb 2021 13:04:49

US3172469

Folder: SAE USA-US118-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:09

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 13:05:45
User entered 'FL'	System	08 Feb 2021 13:04:49

US3172469

Folder: SAE USA-US118-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:09

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'US'	System	08 Feb 2021 13:05:54

US3172469

Folder: SAE USA-US118-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '1'	System	08 Feb 2021 13:05:54

US3172469

Folder: SAE USA-US118-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:09

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 13:05:45
User entered 'USA-US118-2021-MRNA-1273-P301000006'	System	08 Feb 2021 13:04:49

US3172469

Folder: SAE USA-US118-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:09

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 13:05:45
User entered 'Yes (Y)'	System	08 Feb 2021 13:04:49

US3172469

Folder: SAE USA-US118-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:09

Death

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 13:05:45
User entered 'No (N)'	System	08 Feb 2021 13:04:49

US3172469

Folder: SAE USA-US118-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:09

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 13:05:45
User entered 'No (N)'	System	08 Feb 2021 13:04:49

US3172469

Folder: SAE USA-US118-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 13:05:45
User entered 'Yes (Y)'	System	08 Feb 2021 13:04:49

US3172469

Folder: SAE USA-US118-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 13:05:45
User entered 'No (N)'	System	08 Feb 2021 13:04:49

US3172469

Folder: SAE USA-US118-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 13:05:45
User entered 'No (N)'	System	08 Feb 2021 13:04:49

US3172469

Folder: SAE USA-US118-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:09

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 13:05:45
User entered 'No (N)'	System	08 Feb 2021 13:04:49

US3172469

Folder: SAE USA-US118-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:09

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 13:05:45
User entered 'Mark'	System	08 Feb 2021 13:04:49

US3172469

Folder: SAE USA-US118-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:09

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 13:05:45
User entered 'Kutner'	System	08 Feb 2021 13:04:49

US3172469

Folder: SAE USA-US118-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:09

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 13:05:45
User entered 'FL'	System	08 Feb 2021 13:04:49

US3172469

Folder: SAE USA-US118-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:09

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered 'US'	System	08 Feb 2021 13:05:54

US3172469

Folder: SAE USA-US118-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '1'	System	08 Feb 2021 13:05:54

US3172469

Folder: SAE USA-US118-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:32:09

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '08/Feb/2021 13:05'	System	08 Feb 2021 13:05:54

US3172469

Folder: SAE USA-US118-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:32:09

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.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:52:37
User entered '1'	(b) (4), (b) (6)	08 Feb 2021 13:05:54

US3172469

Folder: SAE USA-US118-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:09

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:45:30
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 16:29:24
User entered 'USA-US118-2021-MRNA-1273-P301000016'	System	14 Apr 2021 16:27:25

US3172469

Folder: SAE USA-US118-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:09

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:45:30
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 16:29:24
User entered 'Yes (Y)'	System	14 Apr 2021 16:27:25

US3172469

Folder: SAE USA-US118-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:09

Death

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:45:30
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 16:29:24
User entered 'No (N)'	System	14 Apr 2021 16:27:25

US3172469

Folder: SAE USA-US118-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:09

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:45:30
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 16:29:24
User entered 'No (N)'	System	14 Apr 2021 16:27:25

US3172469

Folder: SAE USA-US118-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:45:30
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 16:29:24
User entered 'Yes (Y)'	System	14 Apr 2021 16:27:25

US3172469

Folder: SAE USA-US118-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:45:30
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 16:29:24
User entered 'No (N)'	System	14 Apr 2021 16:27:25

US3172469

Folder: SAE USA-US118-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:45:30
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 16:29:24
User entered 'No (N)'	System	14 Apr 2021 16:27:25

US3172469

Folder: SAE USA-US118-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:09

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:45:30
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 16:29:24
User entered 'No (N)'	System	14 Apr 2021 16:27:25

US3172469

Folder: SAE USA-US118-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:09

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:45:30
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 16:29:24
User entered 'Mark'	System	14 Apr 2021 16:27:25

US3172469

Folder: SAE USA-US118-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:09

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:45:30
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 16:29:24
User entered 'Kutner'	System	14 Apr 2021 16:27:25

US3172469

Folder: SAE USA-US118-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:09

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:45:30
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 16:29:24
User entered 'FL'	System	14 Apr 2021 16:27:25

US3172469

Folder: SAE USA-US118-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:09

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:45:30
User entered 'US'	System	14 Apr 2021 16:30:01

US3172469

Folder: SAE USA-US118-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Apr 2021 16:30:01

US3172469

Folder: SAE USA-US118-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:09

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:45:30
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 16:29:24
User entered 'USA-US118-2021-MRNA-1273-P301000016'	System	14 Apr 2021 16:27:25

US3172469

Folder: SAE USA-US118-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:09

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:45:30
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 16:29:24
User entered 'Yes (Y)'	System	14 Apr 2021 16:27:25

US3172469

Folder: SAE USA-US118-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:09

Death

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:45:30
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 16:29:24
User entered 'No (N)'	System	14 Apr 2021 16:27:25

US3172469

Folder: SAE USA-US118-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:09

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:45:30
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 16:29:24
User entered 'No (N)'	System	14 Apr 2021 16:27:25

US3172469

Folder: SAE USA-US118-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:45:30
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 16:29:24
User entered 'Yes (Y)'	System	14 Apr 2021 16:27:25

US3172469

Folder: SAE USA-US118-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:45:30
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 16:29:24
User entered 'No (N)'	System	14 Apr 2021 16:27:25

US3172469

Folder: SAE USA-US118-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:45:30
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 16:29:24
User entered 'No (N)'	System	14 Apr 2021 16:27:25

US3172469

Folder: SAE USA-US118-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:09

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:45:30
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 16:29:24
User entered 'No (N)'	System	14 Apr 2021 16:27:25

US3172469

Folder: SAE USA-US118-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:09

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:45:30
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 16:29:24
User entered 'Mark'	System	14 Apr 2021 16:27:25

US3172469

Folder: SAE USA-US118-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:09

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:45:30
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 16:29:24
User entered 'Kutner'	System	14 Apr 2021 16:27:25

US3172469

Folder: SAE USA-US118-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:09

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:45:30
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 16:29:24
User entered 'FL'	System	14 Apr 2021 16:27:25

US3172469

Folder: SAE USA-US118-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:09

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:45:30
User entered 'US'	System	14 Apr 2021 16:30:01

US3172469

Folder: SAE USA-US118-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:32:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Apr 2021 16:30:01

US3172469

Folder: SAE USA-US118-2021-MRNA-1273-P301000016

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:32:09

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:45:30
User entered '14/Apr/2021 09:29'	System	14 Apr 2021 16:30:01

US3172469

Folder: SAE USA-US118-2021-MRNA-1273-P301000016

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:32:09

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.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:45:30
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Apr 2021 16:30:01
User entered '0'	(b) (4), (b) (6)	14 Apr 2021 16:29:38