

US3562229 (Prod: Hope Research Institute LLC - Hunt - PPDS)

Generated By: KC Joubran

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All time stamps listed in this document are displayed in GMT

US3562229

Form: Participant Creation

Data signed: (b) (4) 08 Apr 2021 22:23:13

Generated On: 10 Jun 2021 08:16:08

Participant ID

US3562229

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

US3562229

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 11 Mar 2021 17:36:25

Generated On: 10 Jun 2021 08:16:08

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3562229

Folder: Screening

Form: Demographics

Data signed: (b) (4) 11 Mar 2021 17:36:25

Generated On: 10 Jun 2021 08:16:08

Date of Birth (MMM yyyy)	(b) (6) 1965
Age	55
Age Units	YEARS
Age (Derived)	55
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 11 Mar 2021 17:36:25

Generated On: 10 Jun 2021 08:16:08

Date of Informed Consent (*dd MMM yyyy*) 15 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

US3562229

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 11 Mar 2021 17:36:25

Generated On: 10 Jun 2021 08:16:08

Did the participant meet all eligibility criteria?

Yes

No

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 11 Mar 2021 17:36:25

Generated On: 10 Jun 2021 08:16:08

Were any significant conditions reported?

Yes

No

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 11 Mar 2021 17:36:25

Generated On: 10 Jun 2021 08:16:08

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	UN UNK 2007
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 2007
Start Year (derived)	2007
Stop Month and Year (derived)	
Stop Year (derived)	

US3562229

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 11 Mar 2021 17:36:25

Generated On: 10 Jun 2021 08:16:08

Condition	MILD ASTHMA
Start date (dd MMM yyyy)	UN UNK 2016
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 2016
Start Year (derived)	2016
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 11 Mar 2021 17:36:25

Generated On: 10 Jun 2021 08:16:08

Condition	GASTROESOPHAGEAL REFLUX DISEASE
Start date (dd MMM yyyy)	UN UNK 2003
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 2003
Start Year (derived)	2003
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 11 Mar 2021 17:36:25

Generated On: 10 Jun 2021 08:16:08

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

US3562229

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 11 Mar 2021 17:36:25

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 11 Mar 2021 17:36:25

Generated On: 10 Jun 2021 08:16:08

Condition	ALLERGIC TO KEFLEX
Start date (dd MMM yyyy)	UN UNK 2019
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 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3562229

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 11 Mar 2021 17:36:25

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 11 Mar 2021 17:36:25

Generated On: 10 Jun 2021 08:16:08

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	15 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	11:31 (24 HR)
Vital Signs Date and Time (derived)	15 OCT 2020 11:31
Height (<i>xxx.x</i>)	65.5 in
Weight (<i>xxx.x</i>)	236 lb
BMI (<i>xxx.x</i>)	38.75603 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) 11 Mar 2021 17:36:25

Generated On: 10 Jun 2021 08:16:08

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

15 OCT 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 11 Mar 2021 17:36:25

Generated On: 10 Jun 2021 08:16:08

Date of assessment (*dd MMM yyyy*) 15 OCT 2020

Is the participant of childbearing potential? Yes
No

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

If Partner medically sterile or Other, specify _____

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

Date of surgery unknown False

If Post-menopausal, date of last menstruation (*dd MMM yyyy*) UN UNK 2018

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 11 Mar 2021 17:36:25

Generated On: 10 Jun 2021 08:16:08

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) 11 Mar 2021 17:36:25

Generated On: 10 Jun 2021 08:16:08

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 10 Mar 2021 16:44:31

Generated On: 10 Jun 2021 08:16:08

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 10 Mar 2021 16:44:31

Generated On: 10 Jun 2021 08:16:08

What was the date of randomization? (dd MMM yyyy) 15 OCT 2020

What was the participant's randomization number? 117001

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) 10 Mar 2021 16:44:32

Generated On: 10 Jun 2021 08:16:08

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) 10 Mar 2021 16:44:32

Generated On: 10 Jun 2021 08:16:08

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>)	15 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	11:31 (24 HR)
Vital Signs Date and Time (derived)	15 OCT 2020 11:31
Temperature (<i>xxx.x</i>)	97.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	69 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	153 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	99 mmHg
Diastolic Blood Pressure units	MMHG

US3562229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 10 Mar 2021 16:44:32

Generated On: 10 Jun 2021 08:16:08

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	15 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	12:49 (24 HR)
Vital Signs Date and Time (derived)	15 OCT 2020 12:49
Temperature (<i>xxx.x</i>)	97.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	69 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3562229

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 10 Mar 2021 16:44:31

Generated On: 10 Jun 2021 08:16:08

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.

US3562229

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 10 Mar 2021 16:44:31

Generated On: 10 Jun 2021 08:16:08

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) 15 OCT 2020

What was the treatment time? (00:00-23:59) 12:18 (24 HR)

Treatment Date and Time (derived) 15 OCT 2020 12:18

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

US3562229

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 10 Mar 2021 16:44:31

Generated On: 10 Jun 2021 08:16:08

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	15 OCT 2020
Collection time (<i>00:00-23:59</i>)	11:58 (24 HR)
Collection date and time (derived)	15 OCT 2020 11:58

US3562229

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 10 Mar 2021 16:44:30

Generated On: 10 Jun 2021 08:16:08

Collection date (<i>dd MMM yyyy</i>)			15 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	12:15	15 OCT 2020 12:15
Nasopharyngeal Swab 2	No		

US3562229

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 16:44:31

Generated On: 10 Jun 2021 08:16:08

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3562229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:16:08

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 97.4 °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 15 OCT 2020 12:50

PC Open Date & Time 15 OCT 2020 12:38

PC Close Date & Time 15 OCT 2020 15:08

US3562229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:16:08

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 95.7 °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 15 OCT 2020 20:57
PC Open Date & Time 15 OCT 2020 16:03
PC Close Date & Time 16 OCT 2020 11:59

US3562229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:16:08

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	96.0 °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	16 OCT 2020 18:05
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3562229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:16:08

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	95.4 °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	17 OCT 2020 20:11
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3562229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:16:08

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	96.0 °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	18 OCT 2020 20:22
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3562229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:16:08

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	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	19 OCT 2020 22:52
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3562229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:16:08

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	96.4 °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 OCT 2020 23:40
PC Open Date & Time	20 OCT 2020 12:00
PC Close Date & Time	21 OCT 2020 11:59

US3562229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:16:08

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	97.1 °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	21 OCT 2020 22:10
PC Open Date & Time	21 OCT 2020 12:00
PC Close Date & Time	22 OCT 2020 11:59

US3562229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:16:08

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

15 OCT 2020 12:51

PC Open Date & Time

15 OCT 2020 12:38

PC Close Date & Time

15 OCT 2020 15:08

US3562229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:16:08

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

15 OCT 2020 20:58

PC Open Date & Time

15 OCT 2020 16:03

PC Close Date & Time

16 OCT 2020 11:59

US3562229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:16:08

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	16 OCT 2020 18:05
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3562229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:16:08

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	17 OCT 2020 20:12
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3562229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:16:08

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	18 OCT 2020 20:22
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3562229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:16:08

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	19 OCT 2020 22:52
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3562229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:16:08

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

20 OCT 2020 23:40

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3562229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:16:08

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	21 OCT 2020 22:11
PC Open Date & Time	21 OCT 2020 12:00
PC Close Date & Time	22 OCT 2020 11:59

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:16:08

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

No

Yes

PC Time stamp	15 OCT 2020 12:53
PC Open Date & Time	15 OCT 2020 12:38
PC Close Date & Time	15 OCT 2020 15:08

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:16:08

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

No

Yes

PC Time stamp	15 OCT 2020 20:59
PC Open Date & Time	15 OCT 2020 16:03
PC Close Date & Time	16 OCT 2020 11:59

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:16:08

	Yes <input type="checkbox"/>
PC Time stamp	16 OCT 2020 18:06
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:16:08

Yes

PC Time stamp	18 OCT 2020 20:23
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:16:08

	Yes <input type="checkbox"/>
PC Time stamp	19 OCT 2020 22:53
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:16:08

	Yes <input type="checkbox"/>
PC Time stamp	20 OCT 2020 23:41
PC Open Date & Time	20 OCT 2020 12:00
PC Close Date & Time	21 OCT 2020 11:59

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 16:44:29

Generated On: 10 Jun 2021 08:16:08

Was Contact Attempted?

Yes

No

Date of Contact or Contact Attempt (dd MMM yyyy)

22 OCT 2020

Please select one status for the follow-up contact

Contact Made

Contact Not Made

Comments

If Contact Not Made, please provide Comments

US3562229

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 16:44:29

Generated On: 10 Jun 2021 08:16:08

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3562229

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 16:44:23

Generated On: 10 Jun 2021 08:16:08

Was Contact Attempted?

Yes

No

Date of Contact or Contact Attempt (dd MMM yyyy)

29 OCT 2020

Please select one status for the follow-up contact

Contact Made

Contact Not Made

Comments

If Contact Not Made, please provide Comments

US3562229

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 16:44:23

Generated On: 10 Jun 2021 08:16:08

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3562229

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 16:44:24

Generated On: 10 Jun 2021 08:16:08

Was Contact Attempted? Yes
No

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

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

Comments

If Contact Not Made, please provide Comments

US3562229

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 16:44:23

Generated On: 10 Jun 2021 08:16:08

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3562229

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Mar 2021 22:04:02

Generated On: 10 Jun 2021 08:16:08

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 12 NOV 2020

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

Folder OID VISIT2

US3562229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Mar 2021 22:04:02

Generated On: 10 Jun 2021 08:16:08

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 NOV 2020
Time of assessment (00:00-23:59)	09:57 (24 HR)
Vital Signs Date and Time (derived)	12 NOV 2020 09:57
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	154 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 mmHg
Diastolic Blood Pressure units	MMHG

US3562229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Mar 2021 22:04:02

Generated On: 10 Jun 2021 08:16:08

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 NOV 2020
Time of assessment (00:00-23:59)	11:30 (24 HR)
Vital Signs Date and Time (derived)	12 NOV 2020 11:30
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	100 mmHg
Diastolic Blood Pressure units	MMHG

US3562229

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Mar 2021 22:04:02

Generated On: 10 Jun 2021 08:16:08

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

12 NOV 2020

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

US3562229

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Mar 2021 22:04:02

Generated On: 10 Jun 2021 08:16:08

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) 12 NOV 2020

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

Treatment Date and Time (derived) 12 NOV 2020 11:00

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

US3562229

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Mar 2021 22:04:02

Generated On: 10 Jun 2021 08:16:08

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 12 NOV 2020

Collection time (*00:00-23:59*) 10:27 (24 HR)

Collection date and time (derived) 12 NOV 2020 10:27

US3562229

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Mar 2021 22:04:02

Generated On: 10 Jun 2021 08:16:08

Collection date (<i>dd MMM yyyy</i>)			12 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	10:39	12 NOV 2020 10:39
Nasopharyngeal Swab 2	No		

US3562229

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 22:04:02

Generated On: 10 Jun 2021 08:16:08

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3562229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:16:08

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** 97.5 °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 12 NOV 2020 11:31

PC Open Date & Time 12 NOV 2020 11:20

PC Close Date & Time 12 NOV 2020 13:50

US3562229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:16:08

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 97.3 °F

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

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

PC Time Stamp	12 NOV 2020 21:06
PC Open Date & Time	12 NOV 2020 14:45
PC Close Date & Time	13 NOV 2020 11:59

US3562229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

DAY 2

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.8 °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	13 NOV 2020 18:11
PC Open Date & Time	13 NOV 2020 12:00
PC Close Date & Time	14 NOV 2020 11:59

US3562229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:16:08

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	97.8 °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	14 NOV 2020 20:22
PC Open Date & Time	14 NOV 2020 12:00
PC Close Date & Time	15 NOV 2020 11:59

US3562229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:16:08

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.8 °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	16 NOV 2020 06:14
PC Open Date & Time	15 NOV 2020 12:00
PC Close Date & Time	16 NOV 2020 11:59

US3562229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:16:08

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	97.3 °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	16 NOV 2020 23:02
PC Open Date & Time	16 NOV 2020 12:00
PC Close Date & Time	17 NOV 2020 11:59

US3562229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:16:08

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	97.6 °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	18 NOV 2020 05:59
PC Open Date & Time	17 NOV 2020 12:00
PC Close Date & Time	18 NOV 2020 11:59

US3562229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:16:08

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	18 NOV 2020 12:20
PC Open Date & Time	18 NOV 2020 12:00
PC Close Date & Time	19 NOV 2020 11:59

US3562229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:16:08

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

12 NOV 2020 11:31

PC Open Date & Time

12 NOV 2020 11:20

PC Close Date & Time

12 NOV 2020 13:50

US3562229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:16:08

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 12 NOV 2020 21:06

PC Open Date & Time 12 NOV 2020 14:45

PC Close Date & Time 13 NOV 2020 11:59

US3562229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:16:08

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

13 NOV 2020 18:12

PC Open Date & Time

13 NOV 2020 12:00

PC Close Date & Time

14 NOV 2020 11:59

US3562229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:16:08

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	14 NOV 2020 20:23
PC Open Date & Time	14 NOV 2020 12:00
PC Close Date & Time	15 NOV 2020 11:59

US3562229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:16:08

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	16 NOV 2020 06:14
PC Open Date & Time	15 NOV 2020 12:00
PC Close Date & Time	16 NOV 2020 11:59

US3562229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:16:08

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	16 NOV 2020 23:02
PC Open Date & Time	16 NOV 2020 12:00
PC Close Date & Time	17 NOV 2020 11:59

US3562229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:16:08

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	18 NOV 2020 05:59
PC Open Date & Time	17 NOV 2020 12:00
PC Close Date & Time	18 NOV 2020 11:59

US3562229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:16:08

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

18 NOV 2020 12:20

PC Open Date & Time

18 NOV 2020 12:00

PC Close Date & Time

19 NOV 2020 11:59

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:16:08

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

No

Yes

PC Time stamp	12 NOV 2020 11:32
PC Open Date & Time	12 NOV 2020 11:20
PC Close Date & Time	12 NOV 2020 13:50

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:16:08

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

No
Yes

PC Time stamp	12 NOV 2020 21:07
PC Open Date & Time	12 NOV 2020 14:45
PC Close Date & Time	13 NOV 2020 11:59

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:16:08

	Yes <input type="checkbox"/>
PC Time stamp	13 NOV 2020 18:12
PC Open Date & Time	13 NOV 2020 12:00
PC Close Date & Time	14 NOV 2020 11:59

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:16:08

	Yes <input type="checkbox"/>
PC Time stamp	14 NOV 2020 20:23
PC Open Date & Time	14 NOV 2020 12:00
PC Close Date & Time	15 NOV 2020 11:59

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:16:08

	Yes <input type="checkbox"/>
PC Time stamp	16 NOV 2020 06:15
PC Open Date & Time	15 NOV 2020 12:00
PC Close Date & Time	16 NOV 2020 11:59

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:16:08

	Yes <input type="checkbox"/>
PC Time stamp	16 NOV 2020 23:03
PC Open Date & Time	16 NOV 2020 12:00
PC Close Date & Time	17 NOV 2020 11:59

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:16:08

	Yes <input type="checkbox"/>
PC Time stamp	18 NOV 2020 06:00
PC Open Date & Time	17 NOV 2020 12:00
PC Close Date & Time	18 NOV 2020 11:59

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:16:08

	Yes <input type="checkbox"/>
PC Time stamp	18 NOV 2020 12:20
PC Open Date & Time	18 NOV 2020 12:00
PC Close Date & Time	19 NOV 2020 11:59

US3562229

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 16:44:25

Generated On: 10 Jun 2021 08:16:08

Was Contact Attempted?

Yes

No

Date of Contact or Contact Attempt (dd MMM yyyy)

19 NOV 2020

Please select one status for the follow-up contact

Contact Made

Contact Not Made

Comments

If Contact Not Made, please provide Comments

US3562229

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 16:44:24

Generated On: 10 Jun 2021 08:16:08

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3562229

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 16:44:27

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 16:44:26

Generated On: 10 Jun 2021 08:16:08

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3562229

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 16:44:28

Generated On: 10 Jun 2021 08:16:08

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (dd MMM yyyy) 3 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3562229

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 16:44:27

Generated On: 10 Jun 2021 08:16:08

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3562229

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Mar 2021 22:04:02

Generated On: 10 Jun 2021 08:16:08

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 DEC 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3562229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Mar 2021 22:04:02

Generated On: 10 Jun 2021 08:16:08

Were vital signs assessed? Yes
No

Date of assessment (dd MMM yyyy) 10 DEC 2020

Time of assessment (00:00-23:59) 09:55 (24 HR)

Vital Signs Date and Time (derived) 10 DEC 2020 09:55

Temperature (xxx.x) 97.9 F

Route of measurement Oral
Axillary
Other

If Other, specify _____

Pulse (xxx) 80 beats/min

Pulse units BPM

Respiratory Rate (xxx) 14 breaths/min

Respiratory Rate units BREATHS/MIN

Systolic Blood Pressure (xxx) 130 mmHg

Systolic Blood Pressure units MMHG

Diastolic Blood Pressure (xxx) 86 mmHg

Diastolic Blood Pressure units MMHG

Height (derived) _____

Weight (derived) _____

US3562229

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Mar 2021 22:04:02

Generated On: 10 Jun 2021 08:16:08

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

10 DEC 2020

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

US3562229

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Mar 2021 22:04:02

Generated On: 10 Jun 2021 08:16:08

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 10 DEC 2020

Collection time (*00:00-23:59*) 10:04 (24 HR)

Collection date and time (derived) 10 DEC 2020 10:04

US3562229

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 22:04:02

Generated On: 10 Jun 2021 08:16:08

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

DAY 61

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

No

Yes

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

No

Yes

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

Date and time of submission 15 DEC 2020 04:39:59

Patient Cloud Open Date & Time 12 DEC 2020 00:01

Patient Cloud Close Date & Time 16 DEC 2020 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 DEC 2020 08:57:49
Patient Cloud Open Date & Time	19 DEC 2020 00:01
Patient Cloud Close Date & Time	23 DEC 2020 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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	29 DEC 2020 18:12:57
Patient Cloud Open Date & Time	26 DEC 2020 00:01
Patient Cloud Close Date & Time	30 DEC 2020 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

Yes

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

No

Yes

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

Date and time of submission 03 JAN 2021 18:16:28

Patient Cloud Open Date & Time 02 JAN 2021 00:01

Patient Cloud Close Date & Time 06 JAN 2021 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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	12 JAN 2021 12:15:48
Patient Cloud Open Date & Time	09 JAN 2021 00:01
Patient Cloud Close Date & Time	13 JAN 2021 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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	17 JAN 2021 10:36:45
Patient Cloud Open Date & Time	16 JAN 2021 00:01
Patient Cloud Close Date & Time	20 JAN 2021 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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 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	25 JAN 2021 07:22:52
Patient Cloud Open Date & Time	23 JAN 2021 00:01
Patient Cloud Close Date & Time	27 JAN 2021 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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	02 FEB 2021 16:46:54
Patient Cloud Open Date & Time	30 JAN 2021 00:01
Patient Cloud Close Date & Time	03 FEB 2021 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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	07 FEB 2021 11:31:16
Patient Cloud Open Date & Time	06 FEB 2021 00:01
Patient Cloud Close Date & Time	10 FEB 2021 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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	15 FEB 2021 11:30:04
Patient Cloud Open Date & Time	13 FEB 2021 00:01
Patient Cloud Close Date & Time	17 FEB 2021 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

[Patient Cloud Close Date & Time](#) 24 FEB 2021 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

DAY 138

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

No

Yes

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

No

Yes

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

Date and time of submission

01 MAR 2021 12:00:48

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

DAY 145

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

No

Yes

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

No

Yes

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

Date and time of submission

07 MAR 2021 19:11:09

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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	16 MAR 2021 07:38:29
Patient Cloud Open Date & Time	13 MAR 2021 00:01
Patient Cloud Close Date & Time	17 MAR 2021 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	23 MAR 2021 19:44:43
Patient Cloud Open Date & Time	20 MAR 2021 00:01
Patient Cloud Close Date & Time	24 MAR 2021 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 MAR 2021 11:49:20
Patient Cloud Open Date & Time	27 MAR 2021 00:01
Patient Cloud Close Date & Time	31 MAR 2021 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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	06 APR 2021 16:57:38
Patient Cloud Open Date & Time	03 APR 2021 00:01
Patient Cloud Close Date & Time	07 APR 2021 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

[Patient Cloud Close Date & Time](#)

14 APR 2021 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	20 APR 2021 17:59:59
Patient Cloud Open Date & Time	17 APR 2021 00:01
Patient Cloud Close Date & Time	21 APR 2021 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 APR 2021 12:01:15
Patient Cloud Open Date & Time	24 APR 2021 00:01
Patient Cloud Close Date & Time	28 APR 2021 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 MAY 2021 17:53:56
Patient Cloud Open Date & Time	01 MAY 2021 00:01
Patient Cloud Close Date & Time	05 MAY 2021 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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°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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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°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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 24 JUL 2021 00:01

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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°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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

[Patient Cloud Close Date & Time](#) 18 AUG 2021 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

DAY 334

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

[Patient Cloud Close Date & Time](#) 15 SEP 2021 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

[Patient Cloud Close Date & Time](#) 29 SEP 2021 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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°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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

[Patient Cloud Close Date & Time](#) 06 OCT 2021 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

[Patient Cloud Close Date & Time](#) 13 OCT 2021 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

[Patient Cloud Close Date & Time](#) 27 OCT 2021 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2021 00:01
Patient Cloud Close Date & Time	10 NOV 2021 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

[Patient Cloud Close Date & Time](#) 17 NOV 2021 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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°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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

DAY 425

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

[Patient Cloud Close Date & Time](#)

15 DEC 2021 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

[Patient Cloud Close Date & Time](#)

22 DEC 2021 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

[Patient Cloud Close Date & Time](#)

29 DEC 2021 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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°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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

[Patient Cloud Close Date & Time](#)

20 APR 2022 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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°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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

DAY 621

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

Date and time of submission

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

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

[Patient Cloud Close Date & Time](#)

17 AUG 2022 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

DAY 684

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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°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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

[Patient Cloud Close Date & Time](#) 05 OCT 2022 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills _____

Cough _____

Shortness of breath _____

Difficulty breathing _____

Fatigue _____

Muscle aches _____

Body aches _____

Headache _____

New loss of taste _____

New loss of smell _____

Sore throat _____

Congestion _____

Runny nose _____

Nausea _____

Vomiting _____

Diarrhea _____

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

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 22 OCT 2022 00:01

[Patient Cloud Close Date & Time](#) 26 OCT 2022 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

[Patient Cloud Close Date & Time](#)

02 NOV 2022 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

[Patient Cloud Close Date & Time](#)

09 NOV 2022 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

[Patient Cloud Close Date & Time](#)

16 NOV 2022 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2022 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

[Patient Cloud Close Date & Time](#)

30 NOV 2022 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

Date and time of submission

[Patient Cloud Open Date & Time](#) 03 DEC 2022 00:01

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

[Patient Cloud Close Date & Time](#) 14 DEC 2022 23:59

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

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

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

[Patient Cloud Close Date & Time](#)

21 DEC 2022 23:59

US3562229

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 08:16:08

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		01 MAR 2021 12:00:35

US3562229

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 16:44:29

Generated On: 10 Jun 2021 08:16:08

Was Contact Attempted? Yes
No

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

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

Comments

If Contact Not Made, please provide Comments _____

US3562229

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 16:44:29

Generated On: 10 Jun 2021 08:16:08

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3562229

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 11 Mar 2021 17:36:25

Generated On: 10 Jun 2021 08:16:08

Was Contact Attempted?

Yes

No

Date of Contact or Contact Attempt (dd MMM yyyy)

10 FEB 2021

Please select one status for the follow-up contact

Contact Made

Contact Not Made

Comments

If Contact Not Made, please provide Comments

US3562229

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 11 Mar 2021 17:36:25

Generated On: 10 Jun 2021 08:16:08

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3562229

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 14:10:35

Generated On: 10 Jun 2021 08:16:08

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (dd MMM yyyy) 11 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3562229

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 14:10:35

Generated On: 10 Jun 2021 08:16:08

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3562229

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 20:01:54

Generated On: 10 Jun 2021 08:16:08

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (dd MMM yyyy) 9 APR 2021

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

Comments

If Contact Not Made, please provide Comments

US3562229

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 20:01:54

Generated On: 10 Jun 2021 08:16:08

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3562229

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:16:08

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 _____

US3562229

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:08

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)	_____

US3562229

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:16:08

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.

US3562229

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:16:08

Was the sample collected? Yes
No

Collection date (*dd MMM yyyy*) _____

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

Collection date and time (derived) _____

US3562229

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:08

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

US3562229

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 08:16:08

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"/>

US3562229

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 08:16:08

Generate Next COVID-19 Assessment

Yes

No

US3562229

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

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 22:10:23

Generated On: 10 Jun 2021 08:16:08

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 12 JAN 2021

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

Folder OID UNBLND_DECIDE

US3562229

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

Form: Unblinding

Data signed: (b) (4) 08 Apr 2021 22:10:23

Generated On: 10 Jun 2021 08:16:08

Date of updated informed consent (<i>dd MMM yyyy</i>)	12 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input checked="" type="radio"/> Amendment 6 or later <input type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	30 DEC 2020
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3562229

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 08 Apr 2021 22:10:23

Generated On: 10 Jun 2021 08:16:08

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

US3562229

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 08 Apr 2021 22:10:23

Generated On: 10 Jun 2021 08:16:08

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 JAN 2021
Time of assessment (00:00-23:59)	10:11 (24 HR)
Vital Signs Date and Time (derived)	12 JAN 2021 10:11
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	145 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3562229

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 08 Apr 2021 22:10:23

Generated On: 10 Jun 2021 08:16:08

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 JAN 2021
Time of assessment (00:00-23:59)	11:18 (24 HR)
Vital Signs Date and Time (derived)	12 JAN 2021 11:18
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3562229

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

Form: Physical Examination

Data signed: (b) (4) 08 Apr 2021 22:10:23

Generated On: 10 Jun 2021 08:16:08

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

12 JAN 2021

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

US3562229

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

Form: Exposure

Data signed: (b) (4) 08 Apr 2021 22:10:23

Generated On: 10 Jun 2021 08:16:08

Was study treatment given? Yes
No

If No, reason not given

Participant declined due to Adverse Event
Physician withheld dose due to Adverse Event
Death
Lost To Follow-Up
Physician Decision
Pregnancy
Protocol Deviation
Study Terminated by Sponsor
Withdrawal of Consent by Participant
Confirmed COVID-19
Other

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

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

What was the treatment date? (dd MMM yyyy) 12 JAN 2021

What was the treatment time? (00:00-23:59) 10:48 (24 HR)

Treatment Date and Time (derived) 12 JAN 2021 10:48

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

US3562229

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Apr 2021 22:10:23

Generated On: 10 Jun 2021 08:16:08

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	12 JAN 2021
Collection time (<i>00:00-23:59</i>)	10:20 (24 HR)
Collection date and time (derived)	12 JAN 2021 10:20

US3562229

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 08 Apr 2021 22:10:23

Generated On: 10 Jun 2021 08:16:08

Was the sample collected? Yes No

Collection date (*dd MMM yyyy*) 12 JAN 2021

Collection time (*00:00 - 23:59*) 10:15

Collection Date and Time (derived) 12 JAN 2021 10:15

US3562229

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

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 22:10:23

Generated On: 10 Jun 2021 08:16:08

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3562229

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 11 Mar 2021 17:36:25

Generated On: 10 Jun 2021 08:16:08

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (dd MMM yyyy) 19 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3562229

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 11 Mar 2021 17:36:25

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 22:23:13

Generated On: 10 Jun 2021 08:16:08

Was this visit performed? Yes
No

Visit date (dd MMM yyyy) 11 FEB 2021

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

Folder OID OLD29

US3562229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 08 Apr 2021 22:23:13

Generated On: 10 Jun 2021 08:16:08

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>)	11 FEB 2021
Time of assessment (<i>00:00-23:59</i>)	09:55 (24 HR)
Vital Signs Date and Time (derived)	11 FEB 2021 09:55
Temperature (<i>xxx.x</i>)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	60 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3562229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 08 Apr 2021 22:23:13

Generated On: 10 Jun 2021 08:16:08

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>)	11 FEB 2021
Time of assessment (<i>00:00-23:59</i>)	10:45 (24 HR)
Vital Signs Date and Time (derived)	11 FEB 2021 10:45
Temperature (<i>xxx.x</i>)	97.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	60 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3562229

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Apr 2021 22:23:13

Generated On: 10 Jun 2021 08:16:08

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

11 FEB 2021

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

US3562229

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 08 Apr 2021 22:23:13

Generated On: 10 Jun 2021 08:16:08

Was study treatment given? Yes
No

If No, reason not given

Participant declined due to Adverse Event
Physician withheld dose due to Adverse Event
Death
Lost To Follow-Up
Physician Decision
Pregnancy
Protocol Deviation
Study Terminated by Sponsor
Withdrawal of Consent by Participant
Confirmed COVID-19
Other

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

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

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

What was the treatment time? (00:00-23:59) 10:12 (24 HR)

Treatment Date and Time (derived) 11 FEB 2021 10:12

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

US3562229

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 22:23:13

Generated On: 10 Jun 2021 08:16:08

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3562229

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 11 Mar 2021 17:36:25

Generated On: 10 Jun 2021 08:16:08

Was Contact Attempted? Yes
No

Date of Contact or Contact Attempt (dd MMM yyyy) 19 FEB 2021

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

Comments CONTACT ATTEMPTED ON
19FEB2021, 22FEB2021,
If Contact Not Made, please provide Comments 23FEB2021.

US3562229

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 11 Mar 2021 17:36:25

Generated On: 10 Jun 2021 08:16:08

Is the participant continuing to the next visit?

Yes

No

Continuing Flag

1

US3562229

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 22:23:13

Generated On: 10 Jun 2021 08:16:08

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3562229

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Apr 2021 22:23:13

Generated On: 10 Jun 2021 08:16:08

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	11 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	12:55 (24 HR)
Vital Signs Date and Time (derived)	11 MAR 2021 12:55
Temperature (<i>xxx.x</i>)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse (<i>xxx</i>)	80 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	81 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

US3562229

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Apr 2021 22:23:13

Generated On: 10 Jun 2021 08:16:08

Was the physical examination performed?

Yes

No

Date of examination (dd MMM yyyy)

11 MAR 2021

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

US3562229

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Apr 2021 22:23:13

Generated On: 10 Jun 2021 08:16:08

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	11 MAR 2021
Collection time (<i>00:00-23:59</i>)	13:00 (24 HR)
Collection date and time (derived)	11 MAR 2021 13:00

US3562229

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 08 Apr 2021 22:10:23

Generated On: 10 Jun 2021 08:16:08

Did the participant experience any adverse events?

Yes

No

If Yes, enter details on the Adverse Events form.

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Apr 2021 20:17:59

Generated On: 10 Jun 2021 08:16:08

AEID _____

Adverse event _____ NAUSEA

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) _____ 29 OCT 2020

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

AE start date and time (derived) _____

Ongoing? Yes
No

If not Ongoing, end date (dd MMM yyyy) _____ 30 OCT 2020

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

AE End Date and Time (derived) _____

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

Is the adverse event serious? Yes
No

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy) _____

Hospital Discharge Date (dd MMM yyyy) _____

Admitted to ICU? Yes
No
Unknown

Number of Days in ICU _____

US3562229

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Apr 2021 20:17:59

Generated On: 10 Jun 2021 08:16:08

Persistent or significant disability or incapacity False

Congenital anomaly or birth defect False

Other medically important event False

Relationship to investigational product Not Related
Related
Not Applicable

Relationship to Study Procedure Not Related
Related
Not Applicable

Action taken with investigational product None
Dose Delayed
Investigational Product
Withdrawn
Not Applicable

Other action taken (check all that apply) None

Concomitant Medication False

Concomitant Procedure False

Outcome Fatal
Not Recovered/Not Resolved
Recovered/Resolved
Recovered/Resolved with Sequelae
Recovering/Resolving
Unknown

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____

Narrative _____

Serious Adverse Event Derived (CSA Programming Field Only) 0

Medically Attended AE Derived (CSA Programming Field Only) 0

Admitted to ICU Derived (CSA Programming Field Only) _____

US3562229

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 23 Apr 2021 20:17:59

Generated On: 10 Jun 2021 08:16:08

AEID	
Adverse event	FATIGUE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	29 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	30 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 23 Apr 2021 20:17:59

Generated On: 10 Jun 2021 08:16:08

Persistent or significant disability or incapacity False

Congenital anomaly or birth defect False

Other medically important event False

Relationship to investigational product Not Related
Related
Not Applicable

Relationship to Study Procedure Not Related
Related
Not Applicable

Action taken with investigational product None
Dose Delayed
Investigational Product
Withdrawn
Not Applicable

Other action taken (check all that apply) None

Concomitant Medication False

Concomitant Procedure False

Outcome Fatal
Not Recovered/Not Resolved
Recovered/Resolved
Recovered/Resolved with Sequelae
Recovering/Resolving
Unknown

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____

Narrative _____

Serious Adverse Event Derived (CSA Programming Field Only) 0

Medically Attended AE Derived (CSA Programming Field Only) 0

Admitted to ICU Derived (CSA Programming Field Only) _____

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 23 Apr 2021 20:17:59

Generated On: 10 Jun 2021 08:16:08

AEID	
Adverse event	DIZENESS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	01 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	01 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 23 Apr 2021 20:17:59

Generated On: 10 Jun 2021 08:16:08

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	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3562229

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 23 Apr 2021 20:17:59

Generated On: 10 Jun 2021 08:16:08

AEID	
Adverse event	MUSCLE CRAMPING (BOTH SIDE OF BODY)
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	01 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 23 Apr 2021 20:17:59

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 23 Apr 2021 20:17:59

Generated On: 10 Jun 2021 08:16:08

AEID	
Adverse event	FALL
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	01 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	01 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (6)

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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	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 23 Apr 2021 20:17:59

Generated On: 10 Jun 2021 08:16:08

AEID	
Adverse event	BALANCE ISSUE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	01 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	01 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 23 Apr 2021 20:17:59

Generated On: 10 Jun 2021 08:16:08

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	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 23 Apr 2021 20:17:59

Generated On: 10 Jun 2021 08:16:08

AEID	
Adverse event	TINGLING BOTH SIDE OF THE BODY
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	01 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 23 Apr 2021 20:17:59

Generated On: 10 Jun 2021 08:16:08

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
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	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 23 Apr 2021 20:17:59

Generated On: 10 Jun 2021 08:16:08

AEID USA-US071-2021-MRNA-1273-P30
1000007

Adverse event MILD WEEKNESS OF RIGHT
SIDE PARESTHESIA

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) 16 APR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes
No

If not Ongoing, end date (dd MMM yyyy) 18 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) 16 APR 2021

Hospital Discharge Date (dd MMM yyyy) 18 APR 2021

Admitted to ICU? Yes
No
Unknown

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 23 Apr 2021 20:17:59

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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
Related
Not Applicable

Relationship to Study Procedure Not Related
Related
Not Applicable

Action taken with investigational product None
Dose Delayed
Investigational Product Withdrawn
Not Applicable

Other action taken (check all that apply)

None False

Concomitant Medication False

Concomitant Procedure True

Outcome Fatal
Not Recovered/Not Resolved
Recovered/Resolved
Recovered/Resolved with Sequelae
Recovering/Resolving
Unknown

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____

Narrative _____

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 23 Apr 2021 20:17:59

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THIS IS 56 YR OLD PATIENT WHO WAS ADMITTED AND NEUROLOGY WAS CONSULTED. THE PATIENT INITIALLY HAVE SLURRED SPEECH AND RIGHT SIDED WEAKNESS. SHE ALSO HAVE ISSUE WITH BALANCE. PER MEDICAL RECORDS DID NOT SEE IF COVID 19 TEST WAS DONE AT HOSPITAL OR ED. UPDATED ALL PROCEDURE RELATED TO SAE

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

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Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 23 Apr 2021 20:17:59

Generated On: 10 Jun 2021 08:16:08

AEID _____

Adverse event _____

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) _____

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 _____

Life threatening _____

Requires inpatient or prolongation of existing Hospitalization _____

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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Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 23 Apr 2021 20:17:59

Generated On: 10 Jun 2021 08:16:08

Persistent or significant disability or incapacity _____

Congenital anomaly or birth defect _____

Other medically important event _____

Relationship to investigational product Not Related

Related

Not Applicable

Relationship to Study Procedure Not Related

Related

Not Applicable

Action taken with investigational product None

Dose Delayed

Investigational Product

Withdrawn

Not Applicable

Other action taken (check all that apply) _____

None _____

Concomitant Medication _____

Concomitant Procedure _____

Outcome Fatal

Not Recovered/Not Resolved

Recovered/Resolved

Recovered/Resolved with

Sequelae

Recovering/Resolving

Unknown

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____

Narrative _____

Serious Adverse Event Derived (CSA Programming Field Only) _____

Medically Attended AE Derived (CSA Programming Field Only) _____

Admitted to ICU Derived (CSA Programming Field Only) _____

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 08 Apr 2021 22:10:23

Generated On: 10 Jun 2021 08:16:08

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

Yes

No

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

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 23 Apr 2021 20:18:00

Generated On: 10 Jun 2021 08:16:08

Name of Medication LEVOTHYROXINE

Prophylaxis Yes
No

Indication HYPOTHYROIDISM

Dose per administration 125

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 23 Apr 2021 20:18:00

Generated On: 10 Jun 2021 08:16:08

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) UN UNK 2007

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

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 23 Apr 2021 20:18:00

Generated On: 10 Jun 2021 08:16:08

Name of Medication DULERA

Prophylaxis Yes
No

Indication MILD ASTHMA

Dose per administration 200/5

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 23 Apr 2021 20:18:00

Generated On: 10 Jun 2021 08:16:08

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 2016

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) 2

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 23 Apr 2021 20:18:00

Generated On: 10 Jun 2021 08:16:08

Name of Medication ALBUTEROL SULFATE

Prophylaxis Yes
No

Indication MILD ASTHMA

Dose per administration 180

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 23 Apr 2021 20:18:00

Generated On: 10 Jun 2021 08:16:08

- Intramuscular
- Respiratory (Inhalation)
- Intralesional
- Intraperitoneal
- Nasal
- Vaginal
- Rectal
- Intravenous
- Intravenous Bolus
- Intravenous Drip
- Other

If route of administration is Other, specify _____

Start date (dd MMM yyyy) UN UNK 2016

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 23 Apr 2021 20:18:00

Generated On: 10 Jun 2021 08:16:08

Name of Medication PRILOSEC

Prophylaxis Yes
No

Indication GASTROESOPHAGEAL REFLUX DISEASE

Dose per administration 40

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 23 Apr 2021 20:18:00

Generated On: 10 Jun 2021 08:16:08

	Intraocular	<input type="radio"/>
	Intramuscular	<input 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) UN UNK 2003

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

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 23 Apr 2021 20:18:00

Generated On: 10 Jun 2021 08:16:08

Name of Medication ESTRADIOL

Prophylaxis Yes
No

Indication POST MENOPAUSE SYMPTOMS

Dose per administration 1

Dose unit mg
ug
mL
g
IU
tablet
capsule
puff
Other

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

Route of administration Oral
Topical
Subcutaneous
Transdermal
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 23 Apr 2021 20:18:00

Generated On: 10 Jun 2021 08:16:08

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

If route of administration is Other, specify _____

Start date (dd MMM yyyy) UN UNK 2018

Start date completely unknown False

Ongoing? Yes
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

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 23 Apr 2021 20:18:00

Generated On: 10 Jun 2021 08:16:08

Name of Medication PROGESTERONE

Prophylaxis Yes
No

Indication POST MENOPAUSAL
SYMPTOMS

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 23 Apr 2021 20:18:00

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	Intraocular	<input type="radio"/>
	Intramuscular	<input 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)	UN UNK 2018
Start date completely unknown	False
Ongoing?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

Was this medication taken for solicited event?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 23 Apr 2021 20:18:00

Generated On: 10 Jun 2021 08:16:08

Name of Medication CETIRIZINE

Prophylaxis Yes
No

Indication SEASONAL ALLERGIES

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 23 Apr 2021 20:18:00

Generated On: 10 Jun 2021 08:16:08

- Intramuscular
- Respiratory (Inhalation)
- Intralesional
- Intraperitoneal
- Nasal
- Vaginal
- Rectal
- Intravenous
- Intravenous Bolus
- Intravenous Drip
- Other

If route of administration is Other, specify _____

Start date (dd MMM yyyy) UN UNK 2010

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

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 23 Apr 2021 20:18:00

Generated On: 10 Jun 2021 08:16:08

Name of Medication ASPIRIN

Prophylaxis Yes
No

Indication CARDIAC PROPHYLAXIS

Dose per administration 81

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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US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 23 Apr 2021 20:18:00

Generated On: 10 Jun 2021 08:16:08

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*) 16 APR 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) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802
803
804

US3562229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 23 Apr 2021 20:18:00

Generated On: 10 Jun 2021 08:16:08

Were any concomitant procedures performed?

Yes

No

If yes, please complete Concomitant Procedures form.

US3562229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 23 Apr 2021 20:18:00

Generated On: 10 Jun 2021 08:16:08

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
17 APR 2021	MRI BRAIN	Adverse Event	
17 APR 2021	MRI C-SPINE	Adverse Event	
16 APR 2021	X-RAY CHEST 1 VIEW	Adverse Event	
16 APR 2021	CT ANGIO HEAD/NECK	Adverse Event	
16 APR 2021	ELECTROCARDIOGRAM	Adverse Event	
18 APR 2021	XR SWALLOW FUNCTION VIDEO OR CLINE	Adverse Event	

US3562229

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 08:16:08

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

US3562229

Folder: SAE USA-US071-2021-MRNA-1273-P301000007

Form: Safety Report Form

Data signed: (b) (4) 23 Apr 2021 20:18:00

Generated On: 10 Jun 2021 08:16:08

SAEID	USA-US071-2021-MRNA-1273-P301000007
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	JOSEPH
Investigator's Last Name	DAVIS
Site Address: Street	3900 E CAMEL BACK ROAD
Site Address: City	PHOENIX
Site Address: State	
Site Address: Postal Code	85018
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3562229

Folder: SAE USA-US071-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Data signed: (b) (4) 23 Apr 2021 20:18:00

Generated On: 10 Jun 2021 08:16:08

SAEID	USA-US071-2021-MRNA-1273-P301000007
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	JOSEPH
Investigator's Last Name	DAVIS
Site Address: Street	3900 E CAMEL BACK ROAD
Site Address: City	PHOENIX
Site Address: State	
Site Address: Postal Code	85018
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	22/APR/2021 11:07
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

US3562229

Folder: SAE USA-US071-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Data signed: (b) (4) 23 Apr 2021 20:18:00

Generated On: 10 Jun 2021 08:16:08

SAEID	USA-US071-2021-MRNA-1273-P301000007
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	JOSEPH
Investigator's Last Name	DAVIS
Site Address: Street	3900 E CAMEL BACK ROAD
Site Address: City	PHOENIX
Site Address: State	
Site Address: Postal Code	85018
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	22/APR/2021 11:26
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

US3562229 (Prod: Hope Research Institute LLC - Hunt - PPDS)

US3562229

Form: Participant Creation

Generated On: 10 Jun 2021 08:16:08

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:23:14
User entered 'US3562229'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	15 Oct 2020 18:33:51

US3562229

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:16:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:34:52

US3562229

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered '15 OCT 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	15 Oct 2020 18:33:52

US3562229

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered 'Clinic (Clinic)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:34:52

US3562229

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 08:16:08

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User entered 'SCRN'	System	19 Oct 2020 16:34:52

US3562229

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:16:08

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered (b) (6) 1965'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	15 Oct 2020 18:33:53

US3562229

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:16:08

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered '55'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 19:37:15

US3562229

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:16:08

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User entered 'YEARS'	System	15 Oct 2020 19:37:15

US3562229

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:16:08

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User entered '55'	System	15 Oct 2020 19:37:56

US3562229

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:16:08

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered 'Female (F)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 19:37:15

US3562229

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:16:08

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4) (b) (4)	11 Mar 2021 17:36:25
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	(b) (4), (b) (6)	15 Oct 2020 19:37:15

US3562229

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:16:08

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered 'l'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 19:37:15

US3562229

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:16:08

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 19:37:15

US3562229

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:16:08

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4) (b) (4)	11 Mar 2021 17:36:25
User entered '0'	(b) (4), (b) (6)	15 Oct 2020 19:37:15

US3562229

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:16:08

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 19:37:15

US3562229

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:16:08

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 19:37:15

US3562229

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:16:08

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 19:37:15

US3562229

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:16:08

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 19:37:15

US3562229

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:16:08

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 19:37:15

US3562229

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 08:16:08

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 19:37:15

US3562229

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:16:08

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered '15 Oct 2020'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 19:37:56

US3562229

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User entered 'Oct 2020'	System	15 Oct 2020 19:37:56

US3562229

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User entered '2020'	System	15 Oct 2020 19:37:56

US3562229

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:16:08

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered 'Amendment 4 (4)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 19:37:56

US3562229

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 19:37:56

US3562229

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:16:08

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 19:37:56

US3562229

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:16:08

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4) (b) (4)	11 Mar 2021 17:36:25
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 19:37:56

US3562229

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:16:08

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 19:37:56

US3562229

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:16:08

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	15 Oct 2020 18:33:52

US3562229

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 08:16:08

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User entered 'l'	System	15 Oct 2020 19:38:27

US3562229

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 19:38:27

US3562229

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 08:16:08

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:56:05

US3562229

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:16:08

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User coded data point as SOC: Endocrine disorders, HLT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	19 Oct 2020 17:19:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	19 Oct 2020 17:19:05
Data point term sent to Coder	System	19 Oct 2020 16:57:09
User entered 'hypothyroidism'	Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:56:22

US3562229

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered 'un UNK 2007'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:56:22

US3562229

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:16:08

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:56:22

US3562229

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:16:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:56:22

US3562229

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:56:22

US3562229

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:16:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:56:22

US3562229

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:16:08

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User entered 'Jan 2007'	System	19 Oct 2020 16:56:22

US3562229

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:16:08

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User entered '2007'	System	19 Oct 2020 16:56:22

US3562229

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User entered empty.	System	19 Oct 2020 16:56:22

US3562229

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User entered empty.	System	19 Oct 2020 16:56:22

US3562229

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:16:08

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
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.	(b) (4) Coder Import (b) (4)	19 Oct 2020 17:19:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	19 Oct 2020 17:19:06
Data point term sent to Coder	System	19 Oct 2020 16:57:10
User entered 'mild asthma'	Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:56:33

US3562229

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered 'un UNK 2016'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:56:33

US3562229

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:16:08

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:56:33

US3562229

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:16:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:56:33

US3562229

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:56:33

US3562229

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:16:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:56:33

US3562229

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:16:08

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User entered 'Jan 2016'	System	19 Oct 2020 16:56:33

US3562229

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:16:08

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User entered '2016'	System	19 Oct 2020 16:56:33

US3562229

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User entered empty.	System	19 Oct 2020 16:56:33

US3562229

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User entered empty.	System	19 Oct 2020 16:56:33

US3562229

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:16:08

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User coded data point as SOC: Gastrointestinal disorders, HLT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	19 Oct 2020 17:19:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	19 Oct 2020 17:19:08
Data point term sent to Coder	System	19 Oct 2020 16:57:10
User entered 'gastroesophageal reflux disease'	Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:56:48

US3562229

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered 'un UNK 2003'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:56:48

US3562229

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:16:08

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:56:48

US3562229

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:16:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:56:48

US3562229

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:56:48

US3562229

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:16:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:56:48

US3562229

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User entered 'Jan 2003'	System	19 Oct 2020 16:56:48

US3562229

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:16:08

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User entered '2003'	System	19 Oct 2020 16:56:48

US3562229

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User entered empty.	System	19 Oct 2020 16:56:48

US3562229

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User entered empty.	System	19 Oct 2020 16:56:48

US3562229

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:16:08

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	19 Oct 2020 17:19:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Oct 2020 17:19:07
Data point term sent to Coder	System	19 Oct 2020 16:57:11
User entered 'seasonal allergies'	Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:56:59

US3562229

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered 'un UNK 2010'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:56:59

US3562229

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:16:08

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:56:59

US3562229

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:16:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:56:59

US3562229

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:56:59

US3562229

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:16:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:56:59

US3562229

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:16:08

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User entered 'Jan 2010'	System	19 Oct 2020 16:56:59

US3562229

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:16:08

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User entered '2010'	System	19 Oct 2020 16:56:59

US3562229

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User entered empty.	System	19 Oct 2020 16:56:59

US3562229

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User entered empty.	System	19 Oct 2020 16:56:59

US3562229

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:16:08

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	19 Oct 2020 17:19:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	19 Oct 2020 17:19:05
Data point term sent to Coder	System	19 Oct 2020 16:57:11
User entered 'post menopause'	Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:57:10

US3562229

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered 'un UNK 2018'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:57:10

US3562229

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:16:08

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:57:10

US3562229

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:16:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:57:10

US3562229

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:57:10

US3562229

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:16:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:57:10

US3562229

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:16:08

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User entered 'Jan 2018'	System	19 Oct 2020 16:57:10

US3562229

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:16:08

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User entered '2018'	System	19 Oct 2020 16:57:10

US3562229

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User entered empty.	System	19 Oct 2020 16:57:10

US3562229

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User entered empty.	System	19 Oct 2020 16:57:10

US3562229

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:16:08

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Allergy to antibiotic - version MedDRA\23.0.	Coder Import (b) (4)	23 Jan 2021 18:13:01
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	23 Jan 2021 18:13:01
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Allergic reaction to antibiotics - version MedDRA\23.0.	Coder Import (b) (4)	19 Oct 2020 23:53:28
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	19 Oct 2020 23:53:28
Data point term sent to Coder	System	19 Oct 2020 16:59:13
User entered 'allergic to keflex'	Dhwani Shah (b) (4)	19 Oct 2020 16:58:55

US3562229

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered 'un UNK 2019'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:58:55

US3562229

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:16:08

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:58:55

US3562229

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:16:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:58:55

US3562229

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:58:55

US3562229

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:16:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:58:55

US3562229

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:16:08

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User entered 'Jan 2019'	System	19 Oct 2020 16:58:55

US3562229

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:16:08

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User entered '2019'	System	19 Oct 2020 16:58:55

US3562229

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User entered empty.	System	19 Oct 2020 16:58:55

US3562229

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User entered empty.	System	19 Oct 2020 16:58:55

US3562229

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:16:08

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User coded data point as SOC: Reproductive system and breast disorders, HLG: Menopause related conditions, HLT: Menopausal effects NEC, PT: Menopausal symptoms, LLT: Postmenopausal symptoms - version MedDRA\23.0.	Coder Import (b) (4)	10 Nov 2020 13:33:31
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	10 Nov 2020 13:33:31
Data point term sent to Coder	System	19 Oct 2020 16:59:16
User entered 'post menopause symptoms'	Dhwani Shah (b) (4)	19 Oct 2020 16:59:14

US3562229

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered 'un UNK 2018'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:59:14

US3562229

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:16:08

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:59:14

US3562229

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:16:08

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:59:14

US3562229

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:59:14

US3562229

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:16:08

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:59:14

US3562229

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User entered 'Jan 2018'	System	19 Oct 2020 16:59:14

US3562229

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:16:08

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User entered '2018'	System	19 Oct 2020 16:59:14

US3562229

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User entered empty.	System	19 Oct 2020 16:59:14

US3562229

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User entered empty.	System	19 Oct 2020 16:59:14

US3562229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:38:49

US3562229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered '15 Oct 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:38:49

US3562229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered '11:31'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:38:49

US3562229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User entered '15 Oct 2020 11:31'	System	19 Oct 2020 16:38:49

US3562229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered '65.5' in	(b) (4) Dhwani Shah (b) (4)	19 Oct 2020 16:38:49
DataPoint set to visible.	(b) (4) System	15 Oct 2020 19:38:27

US3562229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered '236' lb	(b) (4) Dhwani Shah (b) (4)	19 Oct 2020 16:38:49
DataPoint set to visible.	(b) (4) System	15 Oct 2020 19:38:27

US3562229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:08

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User entered '38.75603'	System	19 Oct 2020 16:38:49
DataPoint set to visible.	System	15 Oct 2020 19:38:27

US3562229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:08

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User entered 'kg/m2'	System	19 Oct 2020 16:38:49
DataPoint set to visible.	System	15 Oct 2020 19:38:27

US3562229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered missing code ND - Not Done.	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:38:49

US3562229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:38:49

US3562229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:38:49

US3562229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered missing code ND - Not Done.	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:38:49

US3562229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User entered 'bpm'	System	19 Oct 2020 16:38:49

US3562229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered missing code ND - Not Done.	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:38:49

US3562229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User entered 'breaths/min'	System	19 Oct 2020 16:38:49

US3562229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered missing code ND - Not Done.	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:38:49

US3562229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User entered 'mmHg'	System	19 Oct 2020 16:38:49

US3562229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered missing code ND - Not Done.	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:38:49

US3562229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:08

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User entered 'mmHg'	System	19 Oct 2020 16:38:49

US3562229

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:08

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:08

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30

US3562229

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:16:08

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:41:16

US3562229

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 08:16:08

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered '15 Oct 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:41:16

US3562229

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:16:08

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered '15 Oct 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:41:44

US3562229

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:41:44

US3562229

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered 'Post-menopausal (POST-MENOPAUSAL)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:41:44

US3562229

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:16:08

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:41:44

US3562229

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:41:44

US3562229

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:16:08

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:41:44

US3562229

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered 'UN UNK 2018'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:41:44

US3562229

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 08:16:08

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:41:44

US3562229

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:44:44

US3562229

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:44:44

US3562229

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:08

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)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:44:44

US3562229

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:08

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)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:44:44

US3562229

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:44:44

US3562229

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:08

[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)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:44:44

US3562229

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:08

[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)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:44:44

US3562229

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:08

[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)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:44:44

US3562229

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:08

[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)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:44:44

US3562229

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:08

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)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:44:44

US3562229

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:08

[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)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:44:44

US3562229

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:08

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:44:44

US3562229

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:08

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:44:44

US3562229

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:08

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:44:44

US3562229

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:44:44

US3562229

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:08

[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)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:44:44

US3562229

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:08

[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)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:44:44

US3562229

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:08

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)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:44:44

US3562229

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered 'l'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:44:44

US3562229

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:08

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:44:44

US3562229

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 08:16:08

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:45:30
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:44:44

US3562229

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:16:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:45:12

US3562229

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered '15 Oct 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:45:12

US3562229

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered 'Clinic (Clinic)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:45:12

US3562229

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 08:16:08

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User entered 'VISIT1'	System	19 Oct 2020 16:45:12

US3562229

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered '15 OCT 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	15 Oct 2020 18:53:41

US3562229

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered '117001'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	15 Oct 2020 18:53:41

US3562229

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4) (b) (4)	10 Mar 2021 16:44:41
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	15 Oct 2020 18:53:41

US3562229

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:45:56

US3562229

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:45:56

US3562229

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:45:56

US3562229

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:16:08

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:45:56

US3562229

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:16:08

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:45:56

US3562229

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4)	19 Oct 2020 16:45:56
DataPoint set to visible.	(b) (4) System	15 Oct 2020 19:37:56

US3562229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:16:08

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered missing code ND - Not Done.	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:47:23

US3562229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:16:08

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered missing code ND - Not Done.	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:47:23

US3562229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:16:08

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered missing code ND - Not Done.	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:47:23

US3562229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:16:08

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered missing code ND - Not Done.	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:47:23

US3562229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:08

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User accepted default value 'Pre-Dose (PREDOSE)'	Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:47:23

US3562229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:47:23

US3562229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered '15 Oct 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:47:23

US3562229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered '11:31'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:47:23

US3562229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User entered '15 Oct 2020 11:31'	System	19 Oct 2020 16:47:23

US3562229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered '97.4' F	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:47:23

US3562229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered 'Oral (Oral)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:47:23

US3562229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:47:23

US3562229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered '69'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:47:23

US3562229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User entered 'bpm'	System	19 Oct 2020 16:47:23

US3562229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered '16'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:47:23

US3562229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User entered 'breaths/min'	System	19 Oct 2020 16:47:23

US3562229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4) (b) (4)	10 Mar 2021 16:44:41
User closed query 'Per CDM: Systolic Blood Pressure is out of range per protocol. Please indicate if CS or NCS and report as AE, if appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 08:17:49
Query 'Per CDM: Systolic Blood Pressure is out of range per protocol. Please indicate if CS or NCS and report as AE, if appropriate.' answered with 'CONFIRMED NCS' (Site from DM).	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 23:57:39
User opened query 'Per CDM: Systolic Blood Pressure is out of range per protocol. Please indicate if CS or NCS and report as AE, if appropriate.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 13:26:27
User entered '153'	Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:47:23

US3562229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User entered 'mmHg'	System	19 Oct 2020 16:47:23

US3562229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered '99'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:47:23

US3562229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:08

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User entered 'mmHg'	System	19 Oct 2020 16:47:23

US3562229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:16:08

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered missing code ND - Not Done.	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:47:23

US3562229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:16:08

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered missing code ND - Not Done.	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:47:23

US3562229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:08

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User accepted default value 'Post-Dose (POSTDOSE)'	Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:47:23

US3562229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:47:23

US3562229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered '15 Oct 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:47:23

US3562229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered '12:49'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:47:23

US3562229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User entered '15 Oct 2020 12:49'	System	19 Oct 2020 16:47:23

US3562229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered '97.4' F	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:47:23

US3562229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered 'Oral (Oral)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:47:23

US3562229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:47:23

US3562229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered '69'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:47:23

US3562229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User entered 'bpm'	System	19 Oct 2020 16:47:23

US3562229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered '16'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:47:23

US3562229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User entered 'breaths/min'	System	19 Oct 2020 16:47:23

US3562229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered '134'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:47:23

US3562229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User entered 'mmHg'	System	19 Oct 2020 16:47:23

US3562229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered '90'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:47:23

US3562229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:08

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User entered 'mmHg'	System	19 Oct 2020 16:47:23

US3562229

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:16:08

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:47:32

US3562229

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 08:16:08

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:47:32

US3562229

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:16:08

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 19:38:51

US3562229

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:16:08

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 19:38:51

US3562229

Folder: Visit 1 Day 1

Form: Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 19:38:51

US3562229

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:16:08

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User entered 'MRNA-1273 OR PLACEBO'	System	15 Oct 2020 19:38:51

US3562229

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:16:08

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered '15 Oct 2020'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 19:38:51

US3562229

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered '12:18'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 19:38:51

US3562229

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User entered '15 Oct 2020 12:18'	System	15 Oct 2020 19:38:51

US3562229

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 19:38:51

US3562229

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User entered 'ONCE'	System	15 Oct 2020 19:38:51

US3562229

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 08:16:08

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User entered 'INTRAMUSCULAR'	System	15 Oct 2020 19:38:51

US3562229

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:16:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:47:50

US3562229

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:16:08

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered '15 Oct 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:47:50

US3562229

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:16:08

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered '11:58'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:47:50

US3562229

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User entered '15 Oct 2020 11:58'	System	19 Oct 2020 16:47:50

US3562229

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:16:08

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered '15 Oct 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:48:03

US3562229

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:16:08

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:48:03

US3562229

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:16:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:48:03

US3562229

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:16:08

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered '12:15'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:48:03

US3562229

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User entered '15 Oct 2020 12:15'	System	19 Oct 2020 16:48:03

US3562229

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:16:08

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:48:03

US3562229

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:16:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:48:03

US3562229

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:16:08

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:48:03

US3562229

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User entered empty.	System	19 Oct 2020 16:48:03

US3562229

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:48:07

US3562229

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 08:16:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User entered 'l'	System	19 Oct 2020 16:48:07

US3562229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
Data entry locked.	System	15 Oct 2020 19:38:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Oct 2020 19:38:51

US3562229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:16:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-15T12:50:21', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'c75a04c6-cec5-495d-8d0a-5a6aa86cd612' User entered 'Yes (Y)'	System	15 Oct 2020 19:50:53
	System	15 Oct 2020 19:50:53

US3562229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:16:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-15T12:50:34', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'c75a04c6-cec5-495d-8d0a-5a6aa86cd612' User entered '97.4'	System	15 Oct 2020 19:50:53
	System	15 Oct 2020 19:50:53

US3562229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-15T12:50:41', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'c75a04c6-cec5-495d-8d0a-5a6aa86cd612'	System	15 Oct 2020 19:50:53
User entered 'No (N)'	System	15 Oct 2020 19:50:53

US3562229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:16:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-15T12:50:48', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'c75a04c6-cec5-495d-8d0a-5a6aa86cd612' User entered '15 Oct 2020 12:50'	System	15 Oct 2020 19:50:53
	System	15 Oct 2020 19:50:53

US3562229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:16:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '15 Oct 2020 12:38'	System	15 Oct 2020 19:38:51

US3562229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:16:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '15 Oct 2020 15:08'	System	15 Oct 2020 19:38:51

US3562229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
Data entry locked.	System	15 Oct 2020 19:38:51
User entered 'Day 1, after vaccination (at home)'	System	15 Oct 2020 19:38:51

US3562229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:16:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-15T20:57:09', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '71bf68e9-8074-4aaa-b6a6-6356ffa990ce' User entered 'Yes (Y)'	System	16 Oct 2020 03:57:45
	System	16 Oct 2020 03:57:45

US3562229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:16:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-15T20:57:17', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '71bf68e9-8074-4aaa-b6a6-6356ffa990ce' User entered '95.7'	System	16 Oct 2020 03:57:45
	System	16 Oct 2020 03:57:45

US3562229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-15T20:57:21', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '71bf68e9-8074-4aaa-b6a6-6356ffa990ce' User entered 'No (N)'	System	16 Oct 2020 03:57:45
	System	16 Oct 2020 03:57:45

US3562229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:16:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-15T20:57:40', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '71bf68e9-8074-4aaa-b6a6-6356ffa990ce' User entered '15 Oct 2020 20:57'	System	16 Oct 2020 03:57:45
	System	16 Oct 2020 03:57:45

US3562229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:16:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '15 Oct 2020 16:03'	System	15 Oct 2020 19:38:51

US3562229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:16:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '16 Oct 2020 11:59'	System	15 Oct 2020 19:38:51

US3562229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
Data entry locked.	System	15 Oct 2020 19:38:51
User entered 'Day 2'	System	15 Oct 2020 19:38:51

US3562229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:16:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-16T18:05:05', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'd2b2431e-9ad9-4d68-a6bd-ffeb8943fa4c' User entered 'Yes (Y)'	System	17 Oct 2020 01:05:26
	System	17 Oct 2020 01:05:26

US3562229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:16:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-16T18:05:11', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'd2b2431e-9ad9-4d68-a6bd-ffeb8943fa4c'	System	17 Oct 2020 01:05:26
User entered '96.0'	System	17 Oct 2020 01:05:26

US3562229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-16T18:05:15', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'd2b2431e-9ad9-4d68-a6bd-ffeb8943fa4c' User entered 'No (N)'	System	17 Oct 2020 01:05:26
	System	17 Oct 2020 01:05:26

US3562229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:16:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-16T18:05:23', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'd2b2431e-9ad9-4d68-a6bd-ffeb8943fa4c' User entered '16 Oct 2020 18:05'	System	17 Oct 2020 01:05:26
	System	17 Oct 2020 01:05:26

US3562229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:16:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '16 Oct 2020 12:00'	System	15 Oct 2020 19:38:51

US3562229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:16:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '17 Oct 2020 11:59'	System	15 Oct 2020 19:38:51

US3562229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
Data entry locked.	System	15 Oct 2020 19:38:51
User entered 'Day 3'	System	15 Oct 2020 19:38:51

US3562229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:16:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-17T20:11:27', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'e560b4ca-6fb4-45b7-9ad5-6cb5c83d4b75' User entered 'Yes (Y)'	System	18 Oct 2020 03:11:49
	System	18 Oct 2020 03:11:49

US3562229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:16:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-17T20:11:36', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'e560b4ca-6fb4-45b7-9ad5-6cb5c83d4b75'	System	18 Oct 2020 03:11:49
User entered '95.4'	System	18 Oct 2020 03:11:49

US3562229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-17T20:11:41', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'e560b4ca-6fb4-45b7-9ad5-6cb5c83d4b75'	System	18 Oct 2020 03:11:49
User entered 'No (N)'	System	18 Oct 2020 03:11:49

US3562229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:16:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-17T20:11:46', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'e560b4ca-6fb4-45b7-9ad5-6cb5c83d4b75'	System	18 Oct 2020 03:11:49
User entered '17 Oct 2020 20:11'	System	18 Oct 2020 03:11:49

US3562229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:16:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 19:38:51

US3562229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:16:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 19:38:51

US3562229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
Data entry locked.	System	15 Oct 2020 19:38:51
User entered 'Day 4'	System	15 Oct 2020 19:38:51

US3562229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:16:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-18T20:22:03', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '623f0c41-6079-4b9a-b4df-b41cbf26ca86' User entered 'Yes (Y)'	System	19 Oct 2020 03:22:23
	System	19 Oct 2020 03:22:23

US3562229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:16:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-18T20:22:08', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '623f0c41-6079-4b9a-b4df-b41cbf26ca86' User entered '96.0'	System	19 Oct 2020 03:22:23
	System	19 Oct 2020 03:22:23

US3562229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-18T20:22:12', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '623f0c41-6079-4b9a-b4df-b41cbf26ca86'	System	19 Oct 2020 03:22:23
User entered 'No (N)'	System	19 Oct 2020 03:22:23

US3562229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:16:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-18T20:22:22', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '623f0c41-6079-4b9a-b4df-b41cbf26ca86' User entered '18 Oct 2020 20:22'	System	19 Oct 2020 03:22:23
	System	19 Oct 2020 03:22:23

US3562229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:16:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '18 Oct 2020 12:00'	System	15 Oct 2020 19:38:51

US3562229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:16:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '19 Oct 2020 11:59'	System	15 Oct 2020 19:38:51

US3562229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
Data entry locked.	System	15 Oct 2020 19:38:51
User entered 'Day 5'	System	15 Oct 2020 19:38:51

US3562229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:16:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-19T22:52:11', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'bd96d839-eb64-4bc0-99fb-42a24f83495f' User entered 'Yes (Y)'	System	20 Oct 2020 05:52:29
	System	20 Oct 2020 05:52:29

US3562229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:16:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-19T22:52:18', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'bd96d839-eb64-4bc0-99fb-42a24f83495f' User entered '96.5'	System	20 Oct 2020 05:52:29
	System	20 Oct 2020 05:52:29

US3562229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-19T22:52:22', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'bd96d839-eb64-4bc0-99fb-42a24f83495f'	System	20 Oct 2020 05:52:29
User entered 'No (N)'	System	20 Oct 2020 05:52:29

US3562229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:16:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-19T22:52:27', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'bd96d839-eb64-4bc0-99fb-42a24f83495f' User entered '19 Oct 2020 22:52'	System	20 Oct 2020 05:52:29
	System	20 Oct 2020 05:52:29

US3562229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:16:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '19 Oct 2020 12:00'	System	15 Oct 2020 19:38:51

US3562229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:16:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '20 Oct 2020 11:59'	System	15 Oct 2020 19:38:51

US3562229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
Data entry locked.	System	15 Oct 2020 19:38:51
User entered 'Day 6'	System	15 Oct 2020 19:38:51

US3562229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:16:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-20T23:39:51', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '744c5240-9d0b-4e06-9449-41fceb5e4837' User entered 'Yes (Y)'	System	21 Oct 2020 06:40:11
	System	21 Oct 2020 06:40:11

US3562229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:16:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-20T23:40:00', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '744c5240-9d0b-4e06-9449-41fceb5e4837' User entered '96.4'	System	21 Oct 2020 06:40:11
	System	21 Oct 2020 06:40:11

US3562229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-20T23:40:04', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '744c5240-9d0b-4e06-9449-41fceb5e4837' User entered 'No (N)'	System	21 Oct 2020 06:40:11
	System	21 Oct 2020 06:40:11

US3562229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:16:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-20T23:40:08', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '744c5240-9d0b-4e06-9449-41fceb5e4837' User entered '20 Oct 2020 23:40'	System	21 Oct 2020 06:40:11
	System	21 Oct 2020 06:40:11

US3562229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:16:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '20 Oct 2020 12:00'	System	15 Oct 2020 19:38:51

US3562229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:16:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '21 Oct 2020 11:59'	System	15 Oct 2020 19:38:51

US3562229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
Data entry locked.	System	15 Oct 2020 19:38:51
User entered 'Day 7'	System	15 Oct 2020 19:38:51

US3562229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:16:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-21T22:10:31', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '462a887c-4397-4c66-ab8f-8dbf4db2a2da' User entered 'Yes (Y)'	System	22 Oct 2020 05:10:48
	System	22 Oct 2020 05:10:48

US3562229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:16:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-21T22:10:37', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '462a887c-4397-4c66-ab8f-8dbf4db2a2da' User entered '97.1'	System	22 Oct 2020 05:10:48
	System	22 Oct 2020 05:10:48

US3562229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-21T22:10:42', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '462a887c-4397-4c66-ab8f-8dbf4db2a2da'	System	22 Oct 2020 05:10:48
User entered 'No (N)'	System	22 Oct 2020 05:10:48

US3562229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:16:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-21T22:10:47', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '462a887c-4397-4c66-ab8f-8dbf4db2a2da' User entered '21 Oct 2020 22:10'	System	22 Oct 2020 05:10:48
	System	22 Oct 2020 05:10:48

US3562229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:16:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '21 Oct 2020 12:00'	System	15 Oct 2020 19:38:51

US3562229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:16:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '22 Oct 2020 11:59'	System	15 Oct 2020 19:38:51

US3562229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
Data entry locked.	System	15 Oct 2020 19:38:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Oct 2020 19:38:51

US3562229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:16:08

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 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-15T12:51:03', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'dd5858d7-5295-4e1e-a182-d1b17722af2c'	System	15 Oct 2020 19:51:38
User entered 'None (1)'	System	15 Oct 2020 19:51:38

US3562229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-15T12:51:13', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'dd5858d7-5295-4e1e-a182-d1b17722af2c' User entered 'No (N)'	System	15 Oct 2020 19:51:38
	System	15 Oct 2020 19:51:38

US3562229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-15T12:51:17', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'dd5858d7-5295-4e1e-a182-d1b17722af2c' User entered 'No (N)'	System	15 Oct 2020 19:51:38
	System	15 Oct 2020 19:51:38

US3562229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:16:08

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 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-15T12:51:25', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'dd5858d7-5295-4e1e-a182-d1b17722af2c'	System	15 Oct 2020 19:51:38
User entered 'None (1)'	System	15 Oct 2020 19:51:38

US3562229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:16:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-15T12:51:30', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'dd5858d7-5295-4e1e-a182-d1b17722af2c' User entered '15 Oct 2020 12:51'	System	15 Oct 2020 19:51:38
	System	15 Oct 2020 19:51:38

US3562229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:16:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '15 Oct 2020 12:38'	System	15 Oct 2020 19:38:51

US3562229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:16:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '15 Oct 2020 15:08'	System	15 Oct 2020 19:38:51

US3562229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
Data entry locked.	System	15 Oct 2020 19:38:51
User entered 'Day 1, after vaccination (at home)'	System	15 Oct 2020 19:38:51

US3562229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:16:08

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 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-15T20:57:51', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '1360be06-36d3-472f-b510-8b0ec492b5c6'	System	16 Oct 2020 03:58:23
User entered 'None (1)'	System	16 Oct 2020 03:58:23

US3562229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-15T20:57:54', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '1360be06-36d3-472f-b510-8b0ec492b5c6' User entered 'No (N)'	System	16 Oct 2020 03:58:23
	System	16 Oct 2020 03:58:23

US3562229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-15T20:57:58', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '1360be06-36d3-472f-b510-8b0ec492b5c6' User entered 'No (N)'	System	16 Oct 2020 03:58:23
	System	16 Oct 2020 03:58:23

US3562229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:16:08

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 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-15T20:58:17', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '1360be06-36d3-472f-b510-8b0ec492b5c6'	System	16 Oct 2020 03:58:23
User entered 'None (1)'	System	16 Oct 2020 03:58:23

US3562229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:16:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-15T20:58:21', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '1360be06-36d3-472f-b510-8b0ec492b5c6' User entered '15 Oct 2020 20:58'	System	16 Oct 2020 03:58:23
	System	16 Oct 2020 03:58:23

US3562229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:16:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '15 Oct 2020 16:03'	System	15 Oct 2020 19:38:51

US3562229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:16:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '16 Oct 2020 11:59'	System	15 Oct 2020 19:38:51

US3562229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
Data entry locked.	System	15 Oct 2020 19:38:51
User entered 'Day 2'	System	15 Oct 2020 19:38:51

US3562229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:16:08

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 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-16T18:05:30', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'c8900a49-a883-4ea1-ad2d-822eb05de98c' User entered 'None (1)'	System	17 Oct 2020 01:05:48
	System	17 Oct 2020 01:05:48

US3562229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-16T18:05:35', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'c8900a49-a883-4ea1-ad2d-822eb05de98c' User entered 'No (N)'	System	17 Oct 2020 01:05:48
	System	17 Oct 2020 01:05:48

US3562229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-16T18:05:38', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'c8900a49-a883-4ea1-ad2d-822eb05de98c' User entered 'No (N)'	System	17 Oct 2020 01:05:48
	System	17 Oct 2020 01:05:48

US3562229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:16:08

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 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-16T18:05:44', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'c8900a49-a883-4ea1-ad2d-822eb05de98c'	System	17 Oct 2020 01:05:48
User entered 'None (1)'	System	17 Oct 2020 01:05:48

US3562229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:16:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-16T18:05:47', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'c8900a49-a883-4ea1-ad2d-822eb05de98c' User entered '16 Oct 2020 18:05'	System	17 Oct 2020 01:05:48
	System	17 Oct 2020 01:05:48

US3562229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:16:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '16 Oct 2020 12:00'	System	15 Oct 2020 19:38:51

US3562229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:16:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '17 Oct 2020 11:59'	System	15 Oct 2020 19:38:51

US3562229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
Data entry locked.	System	15 Oct 2020 19:38:51
User entered 'Day 3'	System	15 Oct 2020 19:38:51

US3562229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:16:08

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 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-17T20:11:53', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '4ffecaa0-f9af-4c6a-9489-89368d6232a8'	System	18 Oct 2020 03:12:16
User entered 'None (1)'	System	18 Oct 2020 03:12:16

US3562229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-17T20:11:57', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '4ffecaa0-f9af-4c6a-9489-89368d6232a8'	System	18 Oct 2020 03:12:16
User entered 'No (N)'	System	18 Oct 2020 03:12:16

US3562229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-17T20:12:05', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '4ffecaa0-f9af-4c6a-9489-89368d6232a8' User entered 'No (N)'	System	18 Oct 2020 03:12:16
	System	18 Oct 2020 03:12:16

US3562229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:16:08

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 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-17T20:12:08', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '4ffecaa0-f9af-4c6a-9489-89368d6232a8'	System	18 Oct 2020 03:12:16
User entered 'None (1)'	System	18 Oct 2020 03:12:16

US3562229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:16:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-17T20:12:13', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '4ffecaa0-f9af-4c6a-9489-89368d6232a8' User entered '17 Oct 2020 20:12'	System	18 Oct 2020 03:12:16
	System	18 Oct 2020 03:12:16

US3562229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:16:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 19:38:51

US3562229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:16:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 19:38:51

US3562229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
Data entry locked.	System	15 Oct 2020 19:38:51
User entered 'Day 4'	System	15 Oct 2020 19:38:51

US3562229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:16:08

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 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-18T20:22:28', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '81842be3-aeba-4fad-833a-320aca4cb5fa'	System	19 Oct 2020 03:22:44
User entered 'None (1)'	System	19 Oct 2020 03:22:44

US3562229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-18T20:22:32', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '81842be3-aeba-4fad-833a-320aca4cb5fa'	System	19 Oct 2020 03:22:44
User entered 'No (N)'	System	19 Oct 2020 03:22:44

US3562229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-18T20:22:35', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '81842be3-aeba-4fad-833a-320aca4cb5fa' User entered 'No (N)'	System	19 Oct 2020 03:22:44
	System	19 Oct 2020 03:22:44

US3562229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:16:08

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 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-18T20:22:38', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '81842be3-aeba-4fad-833a-320aca4cb5fa'	System	19 Oct 2020 03:22:44
User entered 'None (1)'	System	19 Oct 2020 03:22:44

US3562229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:16:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-18T20:22:40', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '81842be3-aeba-4fad-833a-320aca4cb5fa' User entered '18 Oct 2020 20:22'	System	19 Oct 2020 03:22:44
	System	19 Oct 2020 03:22:44

US3562229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:16:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '18 Oct 2020 12:00'	System	15 Oct 2020 19:38:51

US3562229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:16:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '19 Oct 2020 11:59'	System	15 Oct 2020 19:38:51

US3562229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
Data entry locked.	System	15 Oct 2020 19:38:51
User entered 'Day 5'	System	15 Oct 2020 19:38:51

US3562229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:16:08

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 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-19T22:52:33', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '30ec3c17-5c95-4bb2-93ef-8e3a0b9350fb'	System	20 Oct 2020 05:52:51
User entered 'None (1)'	System	20 Oct 2020 05:52:51

US3562229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-19T22:52:39', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '30ec3c17-5c95-4bb2-93ef-8e3a0b9350fb'	System	20 Oct 2020 05:52:51
User entered 'No (N)'	System	20 Oct 2020 05:52:51

US3562229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-19T22:52:42', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '30ec3c17-5c95-4bb2-93ef-8e3a0b9350fb'	System	20 Oct 2020 05:52:51
User entered 'No (N)'	System	20 Oct 2020 05:52:51

US3562229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:16:08

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 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-19T22:52:46', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '30ec3c17-5c95-4bb2-93ef-8e3a0b9350fb'	System	20 Oct 2020 05:52:51
User entered 'None (1)'	System	20 Oct 2020 05:52:51

US3562229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:16:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-19T22:52:49', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '30ec3c17-5c95-4bb2-93ef-8e3a0b9350fb' User entered '19 Oct 2020 22:52'	System	20 Oct 2020 05:52:51
	System	20 Oct 2020 05:52:51

US3562229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:16:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '19 Oct 2020 12:00'	System	15 Oct 2020 19:38:51

US3562229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:16:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '20 Oct 2020 11:59'	System	15 Oct 2020 19:38:51

US3562229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
Data entry locked.	System	15 Oct 2020 19:38:51
User entered 'Day 6'	System	15 Oct 2020 19:38:51

US3562229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:16:08

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 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-20T23:40:14', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'bb29115d-aa71-41d2-a9d2-11747a214eab'	System	21 Oct 2020 06:40:34
User entered 'None (1)'	System	21 Oct 2020 06:40:34

US3562229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-20T23:40:17', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'bb29115d-aa71-41d2-a9d2-11747a214eab' User entered 'No (N)'	System	21 Oct 2020 06:40:34
	System	21 Oct 2020 06:40:34

US3562229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-20T23:40:22', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'bb29115d-aa71-41d2-a9d2-11747a214eab' User entered 'No (N)'	System	21 Oct 2020 06:40:34
	System	21 Oct 2020 06:40:34

US3562229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:16:08

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 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-20T23:40:27', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'bb29115d-aa71-41d2-a9d2-11747a214eab'	System	21 Oct 2020 06:40:34
User entered 'None (1)'	System	21 Oct 2020 06:40:34

US3562229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:16:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-20T23:40:31', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'bb29115d-aa71-41d2-a9d2-11747a214eab' User entered '20 Oct 2020 23:40'	System	21 Oct 2020 06:40:34
	System	21 Oct 2020 06:40:34

US3562229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:16:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '20 Oct 2020 12:00'	System	15 Oct 2020 19:38:51

US3562229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:16:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '21 Oct 2020 11:59'	System	15 Oct 2020 19:38:51

US3562229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
Data entry locked.	System	15 Oct 2020 19:38:51
User entered 'Day 7'	System	15 Oct 2020 19:38:51

US3562229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:16:08

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 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-21T22:10:52', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '19b801f4-9b32-4698-81ed-56a018869d2b'	System	22 Oct 2020 05:11:11
User entered 'None (1)'	System	22 Oct 2020 05:11:11

US3562229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-21T22:10:56', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '19b801f4-9b32-4698-81ed-56a018869d2b'	System	22 Oct 2020 05:11:11
User entered 'No (N)'	System	22 Oct 2020 05:11:11

US3562229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-21T22:11:02', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '19b801f4-9b32-4698-81ed-56a018869d2b'	System	22 Oct 2020 05:11:11
User entered 'No (N)'	System	22 Oct 2020 05:11:11

US3562229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:16:08

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 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-21T22:11:04', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '19b801f4-9b32-4698-81ed-56a018869d2b'	System	22 Oct 2020 05:11:11
User entered 'None (1)'	System	22 Oct 2020 05:11:11

US3562229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:16:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-21T22:11:10', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '19b801f4-9b32-4698-81ed-56a018869d2b' User entered '21 Oct 2020 22:11'	System	22 Oct 2020 05:11:11
	System	22 Oct 2020 05:11:11

US3562229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:16:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '21 Oct 2020 12:00'	System	15 Oct 2020 19:38:51

US3562229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:16:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '22 Oct 2020 11:59'	System	15 Oct 2020 19:38:51

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
Data entry locked.	System	15 Oct 2020 19:38:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Oct 2020 19:38:51

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:16:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-15T12:52:45', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '39525fac-aeb4-4f4c-9f36-875564d43079' User entered 'None (0)'	System	15 Oct 2020 19:53:18
	System	15 Oct 2020 19:53:18

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:16:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-15T12:52:49', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '39525fac-aeb4-4f4c-9f36-875564d43079' User entered 'None (0)'	System	15 Oct 2020 19:53:18
	System	15 Oct 2020 19:53:18

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:16:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-15T12:52:53', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '39525fac-aeb4-4f4c-9f36-875564d43079' User entered 'None (0)'	System	15 Oct 2020 19:53:18
	System	15 Oct 2020 19:53:18

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:16:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-15T12:52:56', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '39525fac-aeb4-4f4c-9f36-875564d43079' User entered 'None (0)'	System	15 Oct 2020 19:53:18
	System	15 Oct 2020 19:53:18

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:16:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-15T12:53:01', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '39525fac-aeb4-4f4c-9f36-875564d43079' User entered 'None (0)'	System	15 Oct 2020 19:53:18
	System	15 Oct 2020 19:53:18

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:16:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-15T12:53:04', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '39525fac-aeb4-4f4c-9f36-875564d43079' User entered 'None (0)'	System	15 Oct 2020 19:53:18
	System	15 Oct 2020 19:53:18

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:16:08

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 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-15T12:53:09', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '39525fac-aeb4-4f4c-9f36-875564d43079'	System	15 Oct 2020 19:53:18
User entered 'No (N)'	System	15 Oct 2020 19:53:18

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:16:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-15T12:53:13', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '39525fac-aeb4-4f4c-9f36-875564d43079' User entered '15 Oct 2020 12:53'	System	15 Oct 2020 19:53:18
	System	15 Oct 2020 19:53:18

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:16:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '15 Oct 2020 12:38'	System	15 Oct 2020 19:38:51

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:16:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '15 Oct 2020 15:08'	System	15 Oct 2020 19:38:51

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
Data entry locked.	System	15 Oct 2020 19:38:51
User entered 'Day 1, after vaccination (at home)'	System	15 Oct 2020 19:38:51

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:16:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-15T20:58:45', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '77fac08e-b9fb-48b2-84f5-c5b5513f6925'	System	16 Oct 2020 03:59:12
User entered 'None (0)'	System	16 Oct 2020 03:59:12

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:16:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-15T20:58:48', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '77fac08e-b9fb-48b2-84f5-c5b5513f6925'	System	16 Oct 2020 03:59:12
User entered 'None (0)'	System	16 Oct 2020 03:59:12

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:16:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-15T20:58:51', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '77fac08e-b9fb-48b2-84f5-c5b5513f6925'	System	16 Oct 2020 03:59:12
User entered 'None (0)'	System	16 Oct 2020 03:59:12

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:16:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-15T20:58:55', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '77fac08e-b9fb-48b2-84f5-c5b5513f6925' User entered 'None (0)'	System	16 Oct 2020 03:59:12
	System	16 Oct 2020 03:59:12

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:16:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-15T20:58:57', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '77fac08e-b9fb-48b2-84f5-c5b5513f6925'	System	16 Oct 2020 03:59:12
User entered 'None (0)'	System	16 Oct 2020 03:59:12

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:16:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-15T20:59:00', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '77fac08e-b9fb-48b2-84f5-c5b5513f6925' User entered 'None (0)'	System	16 Oct 2020 03:59:12
	System	16 Oct 2020 03:59:12

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:16:08

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 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-15T20:59:04', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '77fac08e-b9fb-48b2-84f5-c5b5513f6925'	System	16 Oct 2020 03:59:12
User entered 'No (N)'	System	16 Oct 2020 03:59:12

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:16:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-15T20:59:07', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '77fac08e-b9fb-48b2-84f5-c5b5513f6925'	System	16 Oct 2020 03:59:12
User entered '15 Oct 2020 20:59'	System	16 Oct 2020 03:59:12

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:16:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '15 Oct 2020 16:03'	System	15 Oct 2020 19:38:51

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:16:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '16 Oct 2020 11:59'	System	15 Oct 2020 19:38:51

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
Data entry locked.	System	15 Oct 2020 19:38:51
User entered 'Day 2'	System	15 Oct 2020 19:38:51

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:16:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-16T18:05:57', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'f76d0a3e-44f7-48ee-bddb-b3ec2b535484' User entered 'None (0)'	System	17 Oct 2020 01:06:42
	System	17 Oct 2020 01:06:42

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:16:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-16T18:06:00', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'f76d0a3e-44f7-48ee-bddb-b3ec2b535484' User entered 'None (0)'	System	17 Oct 2020 01:06:42
	System	17 Oct 2020 01:06:42

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:16:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-16T18:06:08', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'f76d0a3e-44f7-48ee-bddb-b3ec2b535484' User entered 'None (0)'	System	17 Oct 2020 01:06:42
	System	17 Oct 2020 01:06:42

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:16:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-16T18:06:25', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'f76d0a3e-44f7-48ee-bddb-b3ec2b535484' User entered 'None (0)'	System	17 Oct 2020 01:06:42
	System	17 Oct 2020 01:06:42

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:16:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-16T18:06:29', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'f76d0a3e-44f7-48ee-bddb-b3ec2b535484'	System	17 Oct 2020 01:06:42
User entered 'None (0)'	System	17 Oct 2020 01:06:42

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:16:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-16T18:06:32', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'f76d0a3e-44f7-48ee-bddb-b3ec2b535484' User entered 'None (0)'	System	17 Oct 2020 01:06:42
	System	17 Oct 2020 01:06:42

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:16:08

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 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-16T18:06:35', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'f76d0a3e-44f7-48ee-bddb-b3ec2b535484'	System	17 Oct 2020 01:06:42
User entered 'No (N)'	System	17 Oct 2020 01:06:42

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:16:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-16T18:06:39', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'f76d0a3e-44f7-48ee-bddb-b3ec2b535484' User entered '16 Oct 2020 18:06'	System	17 Oct 2020 01:06:42
	System	17 Oct 2020 01:06:42

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:16:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '16 Oct 2020 12:00'	System	15 Oct 2020 19:38:51

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:16:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '17 Oct 2020 11:59'	System	15 Oct 2020 19:38:51

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
Data entry locked.	System	15 Oct 2020 19:38:51
User entered 'Day 3'	System	15 Oct 2020 19:38:51

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:16:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-17T20:12:19', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '9d9e6420-ec8a-4649-a119-6d248341ce29' User entered 'None (0)'	System	18 Oct 2020 03:12:47
	System	18 Oct 2020 03:12:47

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:16:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-17T20:12:23', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '9d9e6420-ec8a-4649-a119-6d248341ce29' User entered 'None (0)'	System	18 Oct 2020 03:12:47
	System	18 Oct 2020 03:12:47

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:16:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-17T20:12:27', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '9d9e6420-ec8a-4649-a119-6d248341ce29' User entered 'None (0)'	System	18 Oct 2020 03:12:47
	System	18 Oct 2020 03:12:47

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:16:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-17T20:12:32', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '9d9e6420-ec8a-4649-a119-6d248341ce29' User entered 'None (0)'	System	18 Oct 2020 03:12:47
	System	18 Oct 2020 03:12:47

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:16:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-17T20:12:34', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '9d9e6420-ec8a-4649-a119-6d248341ce29' User entered 'None (0)'	System	18 Oct 2020 03:12:47
	System	18 Oct 2020 03:12:47

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:16:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-17T20:12:37', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '9d9e6420-ec8a-4649-a119-6d248341ce29' User entered 'None (0)'	System	18 Oct 2020 03:12:47
	System	18 Oct 2020 03:12:47

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:16:08

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 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-17T20:12:40', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '9d9e6420-ec8a-4649-a119-6d248341ce29' User entered 'No (N)'	System	18 Oct 2020 03:12:47
	System	18 Oct 2020 03:12:47

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:16:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-17T20:12:45', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '9d9e6420-ec8a-4649-a119-6d248341ce29' User entered '17 Oct 2020 20:12'	System	18 Oct 2020 03:12:47
	System	18 Oct 2020 03:12:47

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:16:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 19:38:51

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:16:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 19:38:51

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
Data entry locked.	System	15 Oct 2020 19:38:51
User entered 'Day 4'	System	15 Oct 2020 19:38:51

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:16:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-18T20:22:47', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '932ad08d-06b8-4d27-afde-143a81950a3d' User entered 'No interference with activity (1)'	System	19 Oct 2020 03:23:12
	System	19 Oct 2020 03:23:12

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:16:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-18T20:22:50', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '932ad08d-06b8-4d27-afde-143a81950a3d' User entered 'None (0)'	System	19 Oct 2020 03:23:12
	System	19 Oct 2020 03:23:12

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:16:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-18T20:22:53', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '932ad08d-06b8-4d27-afde-143a81950a3d' User entered 'None (0)'	System	19 Oct 2020 03:23:12
	System	19 Oct 2020 03:23:12

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:16:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-18T20:22:57', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '932ad08d-06b8-4d27-afde-143a81950a3d' User entered 'None (0)'	System	19 Oct 2020 03:23:12
	System	19 Oct 2020 03:23:12

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:16:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-18T20:22:59', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '932ad08d-06b8-4d27-afde-143a81950a3d' User entered 'None (0)'	System	19 Oct 2020 03:23:12
	System	19 Oct 2020 03:23:12

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:16:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-18T20:23:01', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '932ad08d-06b8-4d27-afde-143a81950a3d' User entered 'None (0)'	System	19 Oct 2020 03:23:12
	System	19 Oct 2020 03:23:12

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:16:08

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 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-18T20:23:04', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '932ad08d-06b8-4d27-afde-143a81950a3d' User entered 'No (N)'	System	19 Oct 2020 03:23:12
	System	19 Oct 2020 03:23:12

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:16:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-18T20:23:11', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '932ad08d-06b8-4d27-afde-143a81950a3d' User entered '18 Oct 2020 20:23'	System	19 Oct 2020 03:23:12
	System	19 Oct 2020 03:23:12

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:16:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '18 Oct 2020 12:00'	System	15 Oct 2020 19:38:51

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:16:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '19 Oct 2020 11:59'	System	15 Oct 2020 19:38:51

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
Data entry locked.	System	15 Oct 2020 19:38:51
User entered 'Day 5'	System	15 Oct 2020 19:38:51

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:16:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-19T22:52:57', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '235bdf7b-d464-4088-a27a-ca346f712b55'	System	20 Oct 2020 05:53:22
User entered 'No interference with activity (1)'	System	20 Oct 2020 05:53:22

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:16:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-19T22:53:00', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '235bdf7b-d464-4088-a27a-ca346f712b55'	System	20 Oct 2020 05:53:22
User entered 'None (0)'	System	20 Oct 2020 05:53:22

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:16:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-19T22:53:04', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '235bdf7b-d464-4088-a27a-ca346f712b55'	System	20 Oct 2020 05:53:22
User entered 'None (0)'	System	20 Oct 2020 05:53:22

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:16:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-19T22:53:07', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '235bdf7b-d464-4088-a27a-ca346f712b55'	System	20 Oct 2020 05:53:22
User entered 'None (0)'	System	20 Oct 2020 05:53:22

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:16:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-19T22:53:10', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '235bdf7b-d464-4088-a27a-ca346f712b55'	System	20 Oct 2020 05:53:22
User entered 'None (0)'	System	20 Oct 2020 05:53:22

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:16:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-19T22:53:12', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '235bdf7b-d464-4088-a27a-ca346f712b55'	System	20 Oct 2020 05:53:22
User entered 'None (0)'	System	20 Oct 2020 05:53:22

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:16:08

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 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-19T22:53:15', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '235bdf7b-d464-4088-a27a-ca346f712b55'	System	20 Oct 2020 05:53:22
User entered 'No (N)'	System	20 Oct 2020 05:53:22

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:16:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-19T22:53:19', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '235bdf7b-d464-4088-a27a-ca346f712b55'	System	20 Oct 2020 05:53:22
User entered '19 Oct 2020 22:53'	System	20 Oct 2020 05:53:22

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:16:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '19 Oct 2020 12:00'	System	15 Oct 2020 19:38:51

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:16:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '20 Oct 2020 11:59'	System	15 Oct 2020 19:38:51

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
Data entry locked.	System	15 Oct 2020 19:38:51
User entered 'Day 6'	System	15 Oct 2020 19:38:51

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:16:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-20T23:40:37', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '70c6bd00-d8b4-4f53-a671-fa563c7c8a67'	System	21 Oct 2020 06:41:07
User entered 'No interference with activity (1)'	System	21 Oct 2020 06:41:07

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:16:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-20T23:40:41', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '70c6bd00-d8b4-4f53-a671-fa563c7c8a67'	System	21 Oct 2020 06:41:07
User entered 'None (0)'	System	21 Oct 2020 06:41:07

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:16:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-20T23:40:45', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '70c6bd00-d8b4-4f53-a671-fa563c7c8a67'	System	21 Oct 2020 06:41:07
User entered 'None (0)'	System	21 Oct 2020 06:41:07

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:16:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-20T23:40:48', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '70c6bd00-d8b4-4f53-a671-fa563c7c8a67' User entered 'None (0)'	System	21 Oct 2020 06:41:07
	System	21 Oct 2020 06:41:07

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:16:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-20T23:40:53', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '70c6bd00-d8b4-4f53-a671-fa563c7c8a67'	System	21 Oct 2020 06:41:07
User entered 'None (0)'	System	21 Oct 2020 06:41:07

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:16:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-20T23:40:56', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '70c6bd00-d8b4-4f53-a671-fa563c7c8a67'	System	21 Oct 2020 06:41:07
User entered 'None (0)'	System	21 Oct 2020 06:41:07

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:16:08

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 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-20T23:41:00', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '70c6bd00-d8b4-4f53-a671-fa563c7c8a67'	System	21 Oct 2020 06:41:07
User entered 'No (N)'	System	21 Oct 2020 06:41:07

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:16:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-20T23:41:05', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '70c6bd00-d8b4-4f53-a671-fa563c7c8a67' User entered '20 Oct 2020 23:41'	System	21 Oct 2020 06:41:07
	System	21 Oct 2020 06:41:07

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:16:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '20 Oct 2020 12:00'	System	15 Oct 2020 19:38:51

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:16:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '21 Oct 2020 11:59'	System	15 Oct 2020 19:38:51

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
Data entry locked.	System	15 Oct 2020 19:38:51
User entered 'Day 7'	System	15 Oct 2020 19:38:51

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:16:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-21T22:11:16', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '8609c66a-5a41-47b4-8b5c-b9bf469086b9' User entered 'None (0)'	System	22 Oct 2020 05:11:42
	System	22 Oct 2020 05:11:42

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:16:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-21T22:11:19', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '8609c66a-5a41-47b4-8b5c-b9bf469086b9' User entered 'None (0)'	System	22 Oct 2020 05:11:42
	System	22 Oct 2020 05:11:42

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:16:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-21T22:11:22', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '8609c66a-5a41-47b4-8b5c-b9bf469086b9'	System	22 Oct 2020 05:11:42
User entered 'None (0)'	System	22 Oct 2020 05:11:42

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:16:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-21T22:11:24', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '8609c66a-5a41-47b4-8b5c-b9bf469086b9'	System	22 Oct 2020 05:11:42
User entered 'None (0)'	System	22 Oct 2020 05:11:42

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:16:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-21T22:11:26', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '8609c66a-5a41-47b4-8b5c-b9bf469086b9' User entered 'None (0)'	System	22 Oct 2020 05:11:42
	System	22 Oct 2020 05:11:42

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:16:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-21T22:11:28', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '8609c66a-5a41-47b4-8b5c-b9bf469086b9' User entered 'None (0)'	System	22 Oct 2020 05:11:42
	System	22 Oct 2020 05:11:42

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:16:08

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 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-21T22:11:32', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '8609c66a-5a41-47b4-8b5c-b9bf469086b9'	System	22 Oct 2020 05:11:42
User entered 'No (N)'	System	22 Oct 2020 05:11:42

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:16:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-10-21T22:11:38', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '8609c66a-5a41-47b4-8b5c-b9bf469086b9'	System	22 Oct 2020 05:11:42
User entered '21 Oct 2020 22:11'	System	22 Oct 2020 05:11:42

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:16:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '21 Oct 2020 12:00'	System	15 Oct 2020 19:38:51

US3562229

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:16:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '22 Oct 2020 11:59'	System	15 Oct 2020 19:38:51

US3562229

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	22 Oct 2020 21:40:03

US3562229

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered '22 Oct 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	22 Oct 2020 21:40:03

US3562229

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	22 Oct 2020 21:40:03

US3562229

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	22 Oct 2020 21:40:03

US3562229

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	22 Oct 2020 21:40:07

US3562229

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User entered 'l'	System	22 Oct 2020 21:40:07

US3562229

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Oct 2020 23:44:41

US3562229

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered '29 Oct 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Oct 2020 23:44:41

US3562229

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Oct 2020 23:44:41

US3562229

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Oct 2020 23:44:41

US3562229

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Oct 2020 23:44:46

US3562229

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User entered 'l'	System	29 Oct 2020 23:44:46

US3562229

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:27:27

US3562229

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered '5 Nov 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:27:27

US3562229

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:27:27

US3562229

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:27:27

US3562229

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	05 Nov 2020 22:27:33

US3562229

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User entered 'l'	System	05 Nov 2020 22:27:33

US3562229

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:16:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:04:03
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	13 Nov 2020 19:26:57

US3562229

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:04:03
User entered '12 Nov 2020' reason for change: Data Entry Error	(b) (4)	
	Dhwani Shah (b) (4)	13 Nov 2020 19:28:33
User entered '13 Nov 2020'	(b) (4)	
	Dhwani Shah (b) (4)	13 Nov 2020 19:26:57
	(b) (4)	

US3562229

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:04:03
User entered 'Clinic (Clinic)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	13 Nov 2020 19:26:57

US3562229

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:16:08

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User entered 'VISIT2'	System	13 Nov 2020 19:26:57

US3562229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:08

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User accepted default value 'Pre-Dose (PREDOSE)'	Dhwani Shah (b) (4) (b) (4)	13 Nov 2020 19:27:52

US3562229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:04:03
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	13 Nov 2020 19:27:52

US3562229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:08

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4) (b) (4)	12 Mar 2021 22:04:03
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	13 Nov 2020 19:28:52
User entered '12 Nov 2020' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	13 Nov 2020 19:28:52
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	13 Nov 2020 19:28:33
User entered '13 Nov 2020'	Dhwani Shah (b) (4) (b) (4)	13 Nov 2020 19:27:52

US3562229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4) (b) (4)	12 Mar 2021 22:04:03
User closed query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	System	13 Nov 2020 19:28:52
User opened query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	System	13 Nov 2020 19:27:52
User entered '09:57'	Dhwani Shah (b) (4) (b) (4)	13 Nov 2020 19:27:52

US3562229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User entered '12 Nov 2020 09:57'	System	13 Nov 2020 19:28:52
User entered '13 Nov 2020 09:57'	System	13 Nov 2020 19:27:52

US3562229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:04:03
User entered '97.5' F	(b) (4) Dhwani Shah (b) (4) (b) (4)	13 Nov 2020 19:27:52

US3562229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:04:03
User entered 'Oral (Oral)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	13 Nov 2020 19:27:52

US3562229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:04:03
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	13 Nov 2020 19:27:52

US3562229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:04:03
User entered '82'	(b) (4) Dhwani Shah (b) (4) (b) (4)	13 Nov 2020 19:27:52

US3562229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User entered 'bpm'	System	13 Nov 2020 19:27:52

US3562229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:04:03
User entered '16'	(b) (4) Dhwani Shah (b) (4) (b) (4)	13 Nov 2020 19:27:52

US3562229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User entered 'breaths/min'	System	13 Nov 2020 19:27:52

US3562229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4) (b) (4)	12 Mar 2021 22:04:03
User closed query 'Per CDM: Systolic Blood Pressure is out of range per protocol. Please indicate if CS or NCS and report as AE, if appropriate. ' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 08:20:29
Query 'Per CDM: Systolic Blood Pressure is out of range per protocol. Please indicate if CS or NCS and report as AE, if appropriate. ' answered with 'CONFIRMED NCS' (Site from DM).	Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 23:58:29
User opened query 'Per CDM: Systolic Blood Pressure is out of range per protocol. Please indicate if CS or NCS and report as AE, if appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 05:02:26
User entered '154'	Dhwani Shah (b) (4) (b) (4)	13 Nov 2020 19:27:52

US3562229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User entered 'mmHg'	System	13 Nov 2020 19:27:52

US3562229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:04:03
User entered '92'	(b) (4) Dhwani Shah (b) (4) (b) (4)	13 Nov 2020 19:27:52

US3562229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:08

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User entered 'mmHg'	System	13 Nov 2020 19:27:52

US3562229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:08

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User accepted default value 'Post-Dose (POSTDOSE)'	Dhwani Shah (b) (4) (b) (4)	13 Nov 2020 19:27:52

US3562229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:04:03
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	13 Nov 2020 19:27:52

US3562229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:08

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4) (b) (4)	12 Mar 2021 22:04:03
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	13 Nov 2020 19:28:52
User entered '12 Nov 2020' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	13 Nov 2020 19:28:52
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	13 Nov 2020 19:28:33
User entered '13 Nov 2020'	Dhwani Shah (b) (4) (b) (4)	13 Nov 2020 19:27:52

US3562229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:04:03
User entered '11:30'	(b) (4) Dhwani Shah (b) (4) (b) (4)	13 Nov 2020 19:27:52

US3562229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User entered '12 Nov 2020 11:30'	System	13 Nov 2020 19:28:52
User entered '13 Nov 2020 11:30'	System	13 Nov 2020 19:27:52

US3562229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:04:03
User entered '97.5' F	(b) (4) Dhwani Shah (b) (4) (b) (4)	13 Nov 2020 19:27:52

US3562229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:04:03
User entered 'Oral (Oral)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	13 Nov 2020 19:27:52

US3562229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:04:03
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	13 Nov 2020 19:27:52

US3562229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:04:03
User entered '66'	(b) (4) Dhwani Shah (b) (4) (b) (4)	13 Nov 2020 19:27:52

US3562229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User entered 'bpm'	System	13 Nov 2020 19:27:52

US3562229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:04:03
User entered '16'	(b) (4) Dhwani Shah (b) (4) (b) (4)	13 Nov 2020 19:27:52

US3562229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User entered 'breaths/min'	System	13 Nov 2020 19:27:52

US3562229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:04:03
User entered '142'	(b) (4) Dhwani Shah (b) (4) (b) (4)	13 Nov 2020 19:27:52

US3562229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User entered 'mmHg'	System	13 Nov 2020 19:27:52

US3562229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:04:03
User entered '100'	(b) (4) Dhwani Shah (b) (4) (b) (4)	13 Nov 2020 19:27:52

US3562229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:08

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User entered 'mmHg'	System	13 Nov 2020 19:27:52

US3562229

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:16:08

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:04:03
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	13 Nov 2020 19:35:25

US3562229

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:16:08

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:04:03
User entered '12 Nov 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	13 Nov 2020 19:35:25

US3562229

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:16:08

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:04:03
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Nov 2020 18:06:20

US3562229

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:16:08

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:04:03
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Nov 2020 18:06:20

US3562229

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:04:03
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Nov 2020 18:06:20

US3562229

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:16:08

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User entered 'MRNA-1273 OR PLACEBO'	System	12 Nov 2020 18:06:20

US3562229

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:16:08

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4) (b) (4)	12 Mar 2021 22:04:03
User closed query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	System	13 Nov 2020 19:28:33
Query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	13 Nov 2020 19:28:33
User opened query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	System	13 Nov 2020 19:26:57
User entered '12 Nov 2020'	Dhwani Shah (b) (4) (b) (4)	12 Nov 2020 18:06:20

US3562229

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:04:03
User entered '11:00'	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Nov 2020 18:06:20

US3562229

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User entered '12 Nov 2020 11:00'	System	12 Nov 2020 18:06:20

US3562229

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:04:03
User entered 'Left Arm (LEFT ARM)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Nov 2020 18:06:20

US3562229

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User entered 'ONCE'	System	12 Nov 2020 18:06:20

US3562229

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User entered 'INTRAMUSCULAR'	System	12 Nov 2020 18:06:20

US3562229

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:16:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:04:03
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	13 Nov 2020 19:35:46

US3562229

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:16:08

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:04:03
User entered '12 Nov 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	13 Nov 2020 19:35:46

US3562229

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:16:08

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:04:03
User entered '10:27'	(b) (4) Dhwani Shah (b) (4) (b) (4)	13 Nov 2020 19:35:46

US3562229

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User entered '12 Nov 2020 10:27'	System	13 Nov 2020 19:35:46

US3562229

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 08:16:08

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:04:03
User entered '12 Nov 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	13 Nov 2020 19:35:59

US3562229

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:16:08

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Dhwani Shah (b) (4) (b) (4)	13 Nov 2020 19:35:59

US3562229

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:16:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:04:03
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	13 Nov 2020 19:35:59

US3562229

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:16:08

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:04:03
User entered '10:39'	(b) (4) Dhwani Shah (b) (4) (b) (4)	13 Nov 2020 19:35:59

US3562229

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User entered '12 Nov 2020 10:39'	System	13 Nov 2020 19:35:59

US3562229

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:16:08

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Dhwani Shah (b) (4) (b) (4)	13 Nov 2020 19:35:59

US3562229

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:16:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:04:03
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	13 Nov 2020 19:35:59

US3562229

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:16:08

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:04:03
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	13 Nov 2020 19:35:59

US3562229

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User entered empty.	System	13 Nov 2020 19:35:59

US3562229

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:04:03
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	13 Nov 2020 19:36:03

US3562229

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User entered 'l'	System	13 Nov 2020 19:36:03

US3562229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
Data entry locked.	System	12 Nov 2020 18:06:20
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Nov 2020 18:06:20

US3562229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:16:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-12T11:30:52', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'd65f266c-34d3-48a4-82f4-ff54f191b1c5'	System	12 Nov 2020 18:31:11
User entered 'Yes (Y)'	System	12 Nov 2020 18:31:11

US3562229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:16:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-12T11:31:01', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'd65f266c-34d3-48a4-82f4-ff54f191b1c5' User entered '97.5'	System	12 Nov 2020 18:31:11
	System	12 Nov 2020 18:31:11

US3562229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-12T11:31:05', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'd65f266c-34d3-48a4-82f4-ff54f191b1c5'	System	12 Nov 2020 18:31:11
User entered 'No (N)'	System	12 Nov 2020 18:31:11

US3562229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:16:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-12T11:31:09', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'd65f266c-34d3-48a4-82f4-ff54f191b1c5'	System	12 Nov 2020 18:31:11
User entered '12 Nov 2020 11:31'	System	12 Nov 2020 18:31:11

US3562229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:16:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '12 Nov 2020 11:20'	System	12 Nov 2020 18:06:20

US3562229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 08:16:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '12 Nov 2020 13:50'	System	12 Nov 2020 18:06:20

US3562229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
Data entry locked.	System	12 Nov 2020 18:06:20
User entered 'Day 1, after vaccination (at home)'	System	12 Nov 2020 18:06:20

US3562229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:16:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-12T21:06:06', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '116f8541-7a59-4cbb-be62-440a522872dd' User entered 'Yes (Y)'	System	13 Nov 2020 04:06:26
	System	13 Nov 2020 04:06:26

US3562229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:16:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-12T21:06:16', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '116f8541-7a59-4cbb-be62-440a522872dd' User entered '97.3'	System	13 Nov 2020 04:06:26
	System	13 Nov 2020 04:06:26

US3562229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-12T21:06:19', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '116f8541-7a59-4cbb-be62-440a522872dd'	System	13 Nov 2020 04:06:26
User entered 'No (N)'	System	13 Nov 2020 04:06:26

US3562229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:16:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-12T21:06:21', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '116f8541-7a59-4cbb-be62-440a522872dd' User entered '12 Nov 2020 21:06'	System	13 Nov 2020 04:06:26
	System	13 Nov 2020 04:06:26

US3562229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:16:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '12 Nov 2020 14:45'	System	12 Nov 2020 18:06:20

US3562229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 08:16:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '13 Nov 2020 11:59'	System	12 Nov 2020 18:06:20

US3562229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
Data entry locked.	System	12 Nov 2020 18:06:20
User entered 'Day 2'	System	12 Nov 2020 18:06:20

US3562229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:16:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-13T18:11:39', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '06e9579c-edac-419a-9668-2d35b443e2f2'	System	14 Nov 2020 01:11:57
User entered 'Yes (Y)'	System	14 Nov 2020 01:11:57

US3562229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:16:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-13T18:11:46', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '06e9579c-edac-419a-9668-2d35b443e2f2' User entered '97.8'	System	14 Nov 2020 01:11:57
	System	14 Nov 2020 01:11:57

US3562229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-13T18:11:50', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '06e9579c-edac-419a-9668-2d35b443e2f2'	System	14 Nov 2020 01:11:57
User entered 'No (N)'	System	14 Nov 2020 01:11:57

US3562229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:16:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-13T18:11:53', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '06e9579c-edac-419a-9668-2d35b443e2f2' User entered '13 Nov 2020 18:11'	System	14 Nov 2020 01:11:57
	System	14 Nov 2020 01:11:57

US3562229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:16:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '13 Nov 2020 12:00'	System	12 Nov 2020 18:06:20

US3562229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 08:16:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '14 Nov 2020 11:59'	System	12 Nov 2020 18:06:20

US3562229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
Data entry locked.	System	12 Nov 2020 18:06:20
User entered 'Day 3'	System	12 Nov 2020 18:06:20

US3562229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:16:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-14T20:22:44', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '7fa8b4d2-7c7b-475b-969e-2fc398b70f27'	System	15 Nov 2020 03:23:01
User entered 'Yes (Y)'	System	15 Nov 2020 03:23:01

US3562229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:16:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-14T20:22:51', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '7fa8b4d2-7c7b-475b-969e-2fc398b70f27'	System	15 Nov 2020 03:23:01
User entered '97.8'	System	15 Nov 2020 03:23:01

US3562229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-14T20:22:55', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '7fa8b4d2-7c7b-475b-969e-2fc398b70f27'	System	15 Nov 2020 03:23:01
User entered 'No (N)'	System	15 Nov 2020 03:23:01

US3562229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:16:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-14T20:22:57', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '7fa8b4d2-7c7b-475b-969e-2fc398b70f27'	System	15 Nov 2020 03:23:01
User entered '14 Nov 2020 20:22'	System	15 Nov 2020 03:23:01

US3562229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:16:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '14 Nov 2020 12:00'	System	12 Nov 2020 18:06:20

US3562229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 08:16:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '15 Nov 2020 11:59'	System	12 Nov 2020 18:06:20

US3562229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
Data entry locked.	System	12 Nov 2020 18:06:20
User entered 'Day 4'	System	12 Nov 2020 18:06:20

US3562229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:16:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-16T06:14:34', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '74a5a5b3-896d-4aa4-803d-6816e7d76a4b' User entered 'Yes (Y)'	System	16 Nov 2020 13:14:48
	System	16 Nov 2020 13:14:48

US3562229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:16:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-16T06:14:40', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '74a5a5b3-896d-4aa4-803d-6816e7d76a4b' User entered '97.8'	System	16 Nov 2020 13:14:48
	System	16 Nov 2020 13:14:48

US3562229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-16T06:14:43', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '74a5a5b3-896d-4aa4-803d-6816e7d76a4b' User entered 'No (N)'	System	16 Nov 2020 13:14:48
	System	16 Nov 2020 13:14:48

US3562229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:16:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-16T06:14:45', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '74a5a5b3-896d-4aa4-803d-6816e7d76a4b' User entered '16 Nov 2020 06:14'	System	16 Nov 2020 13:14:48
	System	16 Nov 2020 13:14:48

US3562229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:16:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '15 Nov 2020 12:00'	System	12 Nov 2020 18:06:20

US3562229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 08:16:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '16 Nov 2020 11:59'	System	12 Nov 2020 18:06:20

US3562229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
Data entry locked.	System	12 Nov 2020 18:06:20
User entered 'Day 5'	System	12 Nov 2020 18:06:20

US3562229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:16:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-16T23:02:10', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '46a6aeaa-98b4-49c9-9d91-6731a9f90487'	System	17 Nov 2020 06:02:32
User entered 'Yes (Y)'	System	17 Nov 2020 06:02:32

US3562229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:16:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-16T23:02:20', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '46a6aeaa-98b4-49c9-9d91-6731a9f90487' User entered '97.3'	System	17 Nov 2020 06:02:32
	System	17 Nov 2020 06:02:32

US3562229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-16T23:02:23', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '46a6aeaa-98b4-49c9-9d91-6731a9f90487'	System	17 Nov 2020 06:02:32
User entered 'No (N)'	System	17 Nov 2020 06:02:32

US3562229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:16:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-16T23:02:26', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '46a6aeaa-98b4-49c9-9d91-6731a9f90487' User entered '16 Nov 2020 23:02'	System	17 Nov 2020 06:02:32
	System	17 Nov 2020 06:02:32

US3562229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:16:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '16 Nov 2020 12:00'	System	12 Nov 2020 18:06:20

US3562229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 08:16:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '17 Nov 2020 11:59'	System	12 Nov 2020 18:06:20

US3562229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
Data entry locked.	System	12 Nov 2020 18:06:20
User entered 'Day 6'	System	12 Nov 2020 18:06:20

US3562229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:16:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-18T05:59:13', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'aa2580bb-9acd-4f6a-bbfe-31fc820a1780' User entered 'Yes (Y)'	System	18 Nov 2020 12:59:26
	System	18 Nov 2020 12:59:26

US3562229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:16:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-18T05:59:19', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'aa2580bb-9acd-4f6a-bbfe-31fc820a1780' User entered '97.6'	System	18 Nov 2020 12:59:26
	System	18 Nov 2020 12:59:26

US3562229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-18T05:59:22', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'aa2580bb-9acd-4f6a-bbfe-31fc820a1780'	System	18 Nov 2020 12:59:26
User entered 'No (N)'	System	18 Nov 2020 12:59:26

US3562229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:16:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-18T05:59:25', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'aa2580bb-9acd-4f6a-bbfe-31fc820a1780' User entered '18 Nov 2020 05:59'	System	18 Nov 2020 12:59:26
	System	18 Nov 2020 12:59:26

US3562229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:16:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '17 Nov 2020 12:00'	System	12 Nov 2020 18:06:20

US3562229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 08:16:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '18 Nov 2020 11:59'	System	12 Nov 2020 18:06:20

US3562229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
Data entry locked.	System	12 Nov 2020 18:06:20
User entered 'Day 7'	System	12 Nov 2020 18:06:20

US3562229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:16:08

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-18T12:19:57', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '4de37995-b068-4c4e-ac49-68403c63ab3a' User entered 'Yes (Y)'	System	18 Nov 2020 19:20:17
	System	18 Nov 2020 19:20:17

US3562229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:16:08

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-18T12:20:02', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '4de37995-b068-4c4e-ac49-68403c63ab3a' User entered '98.0'	System	18 Nov 2020 19:20:17
	System	18 Nov 2020 19:20:17

US3562229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-18T12:20:09', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '4de37995-b068-4c4e-ac49-68403c63ab3a'	System	18 Nov 2020 19:20:17
User entered 'No (N)'	System	18 Nov 2020 19:20:17

US3562229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:16:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-18T12:20:13', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '4de37995-b068-4c4e-ac49-68403c63ab3a' User entered '18 Nov 2020 12:20'	System	18 Nov 2020 19:20:17
	System	18 Nov 2020 19:20:17

US3562229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:16:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '18 Nov 2020 12:00'	System	12 Nov 2020 18:06:20

US3562229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 08:16:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '19 Nov 2020 11:59'	System	12 Nov 2020 18:06:20

US3562229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
Data entry locked.	System	12 Nov 2020 18:06:20
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Nov 2020 18:06:20

US3562229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:16:08

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 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-12T11:31:19', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '49b5034c-edb4-4d7c-a4e7-4623c7f7d138'	System	12 Nov 2020 18:31:38
User entered 'None (1)'	System	12 Nov 2020 18:31:38

US3562229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-12T11:31:25', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '49b5034c-edb4-4d7c-a4e7-4623c7f7d138'	System	12 Nov 2020 18:31:38
User entered 'No (N)'	System	12 Nov 2020 18:31:38

US3562229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-12T11:31:28', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '49b5034c-edb4-4d7c-a4e7-4623c7f7d138'	System	12 Nov 2020 18:31:38
User entered 'No (N)'	System	12 Nov 2020 18:31:38

US3562229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:16:08

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 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-12T11:31:31', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '49b5034c-edb4-4d7c-a4e7-4623c7f7d138'	System	12 Nov 2020 18:31:38
User entered 'None (1)'	System	12 Nov 2020 18:31:38

US3562229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:16:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-12T11:31:34', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '49b5034c-edb4-4d7c-a4e7-4623c7f7d138' User entered '12 Nov 2020 11:31'	System	12 Nov 2020 18:31:38
	System	12 Nov 2020 18:31:38

US3562229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:16:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '12 Nov 2020 11:20'	System	12 Nov 2020 18:06:20

US3562229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 08:16:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '12 Nov 2020 13:50'	System	12 Nov 2020 18:06:20

US3562229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
Data entry locked.	System	12 Nov 2020 18:06:20
User entered 'Day 1, after vaccination (at home)'	System	12 Nov 2020 18:06:20

US3562229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:16:08

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 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-12T21:06:29', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '4c64602c-117e-4846-8f87-e3e0adf04bbf'	System	13 Nov 2020 04:06:46
User entered 'None (1)'	System	13 Nov 2020 04:06:46

US3562229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-12T21:06:32', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '4c64602c-117e-4846-8f87-e3e0adf04bbf'	System	13 Nov 2020 04:06:46
User entered 'No (N)'	System	13 Nov 2020 04:06:46

US3562229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-12T21:06:35', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '4c64602c-117e-4846-8f87-e3e0adf04bbf'	System	13 Nov 2020 04:06:46
User entered 'No (N)'	System	13 Nov 2020 04:06:46

US3562229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:16:08

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 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-12T21:06:39', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '4c64602c-117e-4846-8f87-e3e0adf04bbf'	System	13 Nov 2020 04:06:46
User entered 'None (1)'	System	13 Nov 2020 04:06:46

US3562229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:16:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-12T21:06:42', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '4c64602c-117e-4846-8f87-e3e0adf04bbf' User entered '12 Nov 2020 21:06'	System	13 Nov 2020 04:06:46
	System	13 Nov 2020 04:06:46

US3562229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:16:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '12 Nov 2020 14:45'	System	12 Nov 2020 18:06:20

US3562229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 08:16:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '13 Nov 2020 11:59'	System	12 Nov 2020 18:06:20

US3562229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
Data entry locked.	System	12 Nov 2020 18:06:20
User entered 'Day 2'	System	12 Nov 2020 18:06:20

US3562229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:16:08

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 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-13T18:11:57', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '536bd281-1328-46d9-a1af-ab8b7fd3304b' User entered 'None (1)'	System	14 Nov 2020 01:12:19
	System	14 Nov 2020 01:12:19

US3562229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-13T18:12:00', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '536bd281-1328-46d9-a1af-ab8b7fd3304b' User entered 'No (N)'	System	14 Nov 2020 01:12:19
	System	14 Nov 2020 01:12:19

US3562229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-13T18:12:04', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '536bd281-1328-46d9-a1af-ab8b7fd3304b' User entered 'No (N)'	System	14 Nov 2020 01:12:19
	System	14 Nov 2020 01:12:19

US3562229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:16:08

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 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-13T18:12:10', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '536bd281-1328-46d9-a1af-ab8b7fd3304b'	System	14 Nov 2020 01:12:19
User entered 'None (1)'	System	14 Nov 2020 01:12:19

US3562229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:16:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-13T18:12:15', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '536bd281-1328-46d9-a1af-ab8b7fd3304b' User entered '13 Nov 2020 18:12'	System	14 Nov 2020 01:12:19
	System	14 Nov 2020 01:12:19

US3562229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:16:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '13 Nov 2020 12:00'	System	12 Nov 2020 18:06:20

US3562229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 08:16:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '14 Nov 2020 11:59'	System	12 Nov 2020 18:06:20

US3562229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
Data entry locked.	System	12 Nov 2020 18:06:20
User entered 'Day 3'	System	12 Nov 2020 18:06:20

US3562229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:16:08

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 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-14T20:23:02', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '222a32cf-bb9d-4f81-a555-01eb41c7e3b9'	System	15 Nov 2020 03:23:14
User entered 'None (1)'	System	15 Nov 2020 03:23:14

US3562229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-14T20:23:05', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '222a32cf-bb9d-4f81-a555-01eb41c7e3b9'	System	15 Nov 2020 03:23:14
User entered 'No (N)'	System	15 Nov 2020 03:23:14

US3562229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-14T20:23:07', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '222a32cf-bb9d-4f81-a555-01eb41c7e3b9' User entered 'No (N)'	System	15 Nov 2020 03:23:14
	System	15 Nov 2020 03:23:14

US3562229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:16:08

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 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-14T20:23:09', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '222a32cf-bb9d-4f81-a555-01eb41c7e3b9'	System	15 Nov 2020 03:23:14
User entered 'None (1)'	System	15 Nov 2020 03:23:14

US3562229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:16:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-14T20:23:12', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '222a32cf-bb9d-4f81-a555-01eb41c7e3b9' User entered '14 Nov 2020 20:23'	System	15 Nov 2020 03:23:14
	System	15 Nov 2020 03:23:14

US3562229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:16:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '14 Nov 2020 12:00'	System	12 Nov 2020 18:06:20

US3562229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 08:16:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '15 Nov 2020 11:59'	System	12 Nov 2020 18:06:20

US3562229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
Data entry locked.	System	12 Nov 2020 18:06:20
User entered 'Day 4'	System	12 Nov 2020 18:06:20

US3562229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:16:08

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 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-16T06:14:49', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'd2e7f372-bb34-4e31-81ee-1eee0aff701e'	System	16 Nov 2020 13:14:59
User entered 'None (1)'	System	16 Nov 2020 13:14:59

US3562229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-16T06:14:51', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'd2e7f372-bb34-4e31-81ee-1eee0aff701e'	System	16 Nov 2020 13:14:59
User entered 'No (N)'	System	16 Nov 2020 13:14:59

US3562229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-16T06:14:53', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'd2e7f372-bb34-4e31-81ee-1eee0aff701e' User entered 'No (N)'	System	16 Nov 2020 13:14:59
	System	16 Nov 2020 13:14:59

US3562229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:16:08

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 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-16T06:14:54', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'd2e7f372-bb34-4e31-81ee-1eee0aff701e'	System	16 Nov 2020 13:14:59
User entered 'None (1)'	System	16 Nov 2020 13:14:59

US3562229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:16:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-16T06:14:57', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'd2e7f372-bb34-4e31-81ee-1eee0aff701e' User entered '16 Nov 2020 06:14'	System	16 Nov 2020 13:14:59
	System	16 Nov 2020 13:14:59

US3562229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:16:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '15 Nov 2020 12:00'	System	12 Nov 2020 18:06:20

US3562229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 08:16:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '16 Nov 2020 11:59'	System	12 Nov 2020 18:06:20

US3562229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
Data entry locked.	System	12 Nov 2020 18:06:20
User entered 'Day 5'	System	12 Nov 2020 18:06:20

US3562229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:16:08

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 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-16T23:02:31', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '0864c1a7-d370-49f6-b1b9-51a1660e65b4'	System	17 Nov 2020 06:02:49
User entered 'None (1)'	System	17 Nov 2020 06:02:49

US3562229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-16T23:02:36', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '0864c1a7-d370-49f6-b1b9-51a1660e65b4'	System	17 Nov 2020 06:02:49
User entered 'No (N)'	System	17 Nov 2020 06:02:49

US3562229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-16T23:02:39', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '0864c1a7-d370-49f6-b1b9-51a1660e65b4'	System	17 Nov 2020 06:02:49
User entered 'No (N)'	System	17 Nov 2020 06:02:49

US3562229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:16:08

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 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-16T23:02:43', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '0864c1a7-d370-49f6-b1b9-51a1660e65b4'	System	17 Nov 2020 06:02:49
User entered 'None (1)'	System	17 Nov 2020 06:02:49

US3562229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:16:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-16T23:02:46', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '0864c1a7-d370-49f6-b1b9-51a1660e65b4' User entered '16 Nov 2020 23:02'	System	17 Nov 2020 06:02:49
	System	17 Nov 2020 06:02:49

US3562229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:16:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '16 Nov 2020 12:00'	System	12 Nov 2020 18:06:20

US3562229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 08:16:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '17 Nov 2020 11:59'	System	12 Nov 2020 18:06:20

US3562229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
Data entry locked.	System	12 Nov 2020 18:06:20
User entered 'Day 6'	System	12 Nov 2020 18:06:20

US3562229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:16:08

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 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-18T05:59:29', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '621314c9-3f3f-4474-ab41-7bc215915a0f' User entered 'None (1)'	System	18 Nov 2020 12:59:48
	System	18 Nov 2020 12:59:48

US3562229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-18T05:59:32', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '621314c9-3f3f-4474-ab41-7bc215915a0f' User entered 'No (N)'	System	18 Nov 2020 12:59:48
	System	18 Nov 2020 12:59:48

US3562229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-18T05:59:36', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '621314c9-3f3f-4474-ab41-7bc215915a0f' User entered 'No (N)'	System	18 Nov 2020 12:59:48
	System	18 Nov 2020 12:59:48

US3562229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:16:08

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 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-18T05:59:39', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '621314c9-3f3f-4474-ab41-7bc215915a0f' User entered 'None (1)'	System	18 Nov 2020 12:59:48
	System	18 Nov 2020 12:59:48

US3562229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:16:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-18T05:59:42', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '621314c9-3f3f-4474-ab41-7bc215915a0f' User entered '18 Nov 2020 05:59'	System	18 Nov 2020 12:59:48
	System	18 Nov 2020 12:59:48

US3562229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:16:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '17 Nov 2020 12:00'	System	12 Nov 2020 18:06:20

US3562229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 08:16:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '18 Nov 2020 11:59'	System	12 Nov 2020 18:06:20

US3562229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
Data entry locked.	System	12 Nov 2020 18:06:20
User entered 'Day 7'	System	12 Nov 2020 18:06:20

US3562229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:16:08

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 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-18T12:20:16', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '3395a8e5-9bf1-4c55-8677-cb3292220aed' User entered 'None (1)'	System	18 Nov 2020 19:20:33
	System	18 Nov 2020 19:20:33

US3562229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-18T12:20:18', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '3395a8e5-9bf1-4c55-8677-cb3292220aed' User entered 'No (N)'	System	18 Nov 2020 19:20:33
	System	18 Nov 2020 19:20:33

US3562229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-18T12:20:19', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '3395a8e5-9bf1-4c55-8677-cb3292220aed' User entered 'No (N)'	System	18 Nov 2020 19:20:33
	System	18 Nov 2020 19:20:33

US3562229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:16:08

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 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-18T12:20:21', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '3395a8e5-9bf1-4c55-8677-cb3292220aed'	System	18 Nov 2020 19:20:33
User entered 'None (1)'	System	18 Nov 2020 19:20:33

US3562229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:16:08

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-18T12:20:31', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '3395a8e5-9bf1-4c55-8677-cb3292220aed' User entered '18 Nov 2020 12:20'	System	18 Nov 2020 19:20:33
	System	18 Nov 2020 19:20:33

US3562229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:16:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '18 Nov 2020 12:00'	System	12 Nov 2020 18:06:20

US3562229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 08:16:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '19 Nov 2020 11:59'	System	12 Nov 2020 18:06:20

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
Data entry locked.	System	12 Nov 2020 18:06:20
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Nov 2020 18:06:20

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:16:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-12T11:31:40', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'f2d4a44a-468f-41ac-806f-913f19bf5dcb' User entered 'None (0)'	System	12 Nov 2020 18:32:10
	System	12 Nov 2020 18:32:10

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:16:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-12T11:31:42', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'f2d4a44a-468f-41ac-806f-913f19bf5dcb' User entered 'None (0)'	System	12 Nov 2020 18:32:10
	System	12 Nov 2020 18:32:10

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:16:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-12T11:31:45', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'f2d4a44a-468f-41ac-806f-913f19bf5dcb' User entered 'None (0)'	System	12 Nov 2020 18:32:10
	System	12 Nov 2020 18:32:10

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:16:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-12T11:31:50', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'f2d4a44a-468f-41ac-806f-913f19bf5dcb' User entered 'None (0)'	System	12 Nov 2020 18:32:10
	System	12 Nov 2020 18:32:10

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:16:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-12T11:31:52', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'f2d4a44a-468f-41ac-806f-913f19bf5dcb' User entered 'None (0)'	System	12 Nov 2020 18:32:10
	System	12 Nov 2020 18:32:10

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:16:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-12T11:31:54', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'f2d4a44a-468f-41ac-806f-913f19bf5dcb' User entered 'None (0)'	System	12 Nov 2020 18:32:10
	System	12 Nov 2020 18:32:10

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:16:08

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 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-12T11:31:58', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'f2d4a44a-468f-41ac-806f-913f19bf5dcb'	System	12 Nov 2020 18:32:10
User entered 'No (N)'	System	12 Nov 2020 18:32:10

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:16:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-12T11:32:01', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'f2d4a44a-468f-41ac-806f-913f19bf5dcb' User entered '12 Nov 2020 11:32'	System	12 Nov 2020 18:32:10
	System	12 Nov 2020 18:32:10

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:16:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '12 Nov 2020 11:20'	System	12 Nov 2020 18:06:20

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 08:16:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '12 Nov 2020 13:50'	System	12 Nov 2020 18:06:20

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
Data entry locked.	System	12 Nov 2020 18:06:20
User entered 'Day 1, after vaccination (at home)'	System	12 Nov 2020 18:06:20

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:16:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-12T21:06:47', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '958c4285-7d65-4356-904a-afa10db82377'	System	13 Nov 2020 04:07:13
User entered 'None (0)'	System	13 Nov 2020 04:07:13

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:16:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-12T21:06:49', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '958c4285-7d65-4356-904a-afa10db82377'	System	13 Nov 2020 04:07:13
User entered 'None (0)'	System	13 Nov 2020 04:07:13

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:16:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-12T21:06:56', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '958c4285-7d65-4356-904a-afa10db82377'	System	13 Nov 2020 04:07:13
User entered 'None (0)'	System	13 Nov 2020 04:07:13

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:16:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-12T21:06:59', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '958c4285-7d65-4356-904a-afa10db82377'	System	13 Nov 2020 04:07:13
User entered 'None (0)'	System	13 Nov 2020 04:07:13

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:16:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-12T21:07:00', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '958c4285-7d65-4356-904a-afa10db82377'	System	13 Nov 2020 04:07:13
User entered 'None (0)'	System	13 Nov 2020 04:07:13

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:16:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-12T21:07:02', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '958c4285-7d65-4356-904a-afa10db82377'	System	13 Nov 2020 04:07:13
User entered 'None (0)'	System	13 Nov 2020 04:07:13

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:16:08

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 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-12T21:07:05', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '958c4285-7d65-4356-904a-afa10db82377'	System	13 Nov 2020 04:07:13
User entered 'No (N)'	System	13 Nov 2020 04:07:13

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:16:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-12T21:07:08', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '958c4285-7d65-4356-904a-afa10db82377'	System	13 Nov 2020 04:07:13
User entered '12 Nov 2020 21:07'	System	13 Nov 2020 04:07:13

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:16:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '12 Nov 2020 14:45'	System	12 Nov 2020 18:06:20

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 08:16:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '13 Nov 2020 11:59'	System	12 Nov 2020 18:06:20

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
Data entry locked.	System	12 Nov 2020 18:06:20
User entered 'Day 2'	System	12 Nov 2020 18:06:20

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:16:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-13T18:12:18', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '05d47e16-5f7c-430a-a0eb-156a47688a92' User entered 'None (0)'	System	14 Nov 2020 01:12:35
	System	14 Nov 2020 01:12:35

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:16:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-13T18:12:20', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '05d47e16-5f7c-430a-a0eb-156a47688a92' User entered 'None (0)'	System	14 Nov 2020 01:12:35
	System	14 Nov 2020 01:12:35

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:16:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-13T18:12:22', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '05d47e16-5f7c-430a-a0eb-156a47688a92'	System	14 Nov 2020 01:12:35
User entered 'None (0)'	System	14 Nov 2020 01:12:35

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:16:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-13T18:12:23', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '05d47e16-5f7c-430a-a0eb-156a47688a92' User entered 'None (0)'	System	14 Nov 2020 01:12:35
	System	14 Nov 2020 01:12:35

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:16:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-13T18:12:25', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '05d47e16-5f7c-430a-a0eb-156a47688a92'	System	14 Nov 2020 01:12:35
User entered 'None (0)'	System	14 Nov 2020 01:12:35

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:16:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-13T18:12:27', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '05d47e16-5f7c-430a-a0eb-156a47688a92'	System	14 Nov 2020 01:12:35
User entered 'None (0)'	System	14 Nov 2020 01:12:35

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:16:08

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 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-13T18:12:29', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '05d47e16-5f7c-430a-a0eb-156a47688a92'	System	14 Nov 2020 01:12:35
User entered 'No (N)'	System	14 Nov 2020 01:12:35

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:16:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-13T18:12:32', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '05d47e16-5f7c-430a-a0eb-156a47688a92'	System	14 Nov 2020 01:12:35
User entered '13 Nov 2020 18:12'	System	14 Nov 2020 01:12:35

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:16:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '13 Nov 2020 12:00'	System	12 Nov 2020 18:06:20

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 08:16:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '14 Nov 2020 11:59'	System	12 Nov 2020 18:06:20

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
Data entry locked.	System	12 Nov 2020 18:06:20
User entered 'Day 3'	System	12 Nov 2020 18:06:20

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:16:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-14T20:23:16', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'cb53a4c2-df4d-423e-8c9a-0baef2f91e3d' User entered 'None (0)'	System	15 Nov 2020 03:23:36
	System	15 Nov 2020 03:23:36

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:16:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-14T20:23:18', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'cb53a4c2-df4d-423e-8c9a-0baef2f91e3d' User entered 'None (0)'	System	15 Nov 2020 03:23:36
	System	15 Nov 2020 03:23:36

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:16:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-14T20:23:20', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'cb53a4c2-df4d-423e-8c9a-0baef2f91e3d' User entered 'None (0)'	System	15 Nov 2020 03:23:36
	System	15 Nov 2020 03:23:36

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:16:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-14T20:23:25', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'cb53a4c2-df4d-423e-8c9a-0baef2f91e3d' User entered 'None (0)'	System	15 Nov 2020 03:23:36
	System	15 Nov 2020 03:23:36

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:16:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-14T20:23:27', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'cb53a4c2-df4d-423e-8c9a-0baef2f91e3d' User entered 'None (0)'	System	15 Nov 2020 03:23:36
	System	15 Nov 2020 03:23:36

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:16:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-14T20:23:28', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'cb53a4c2-df4d-423e-8c9a-0baef2f91e3d' User entered 'None (0)'	System	15 Nov 2020 03:23:36
	System	15 Nov 2020 03:23:36

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:16:08

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 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-14T20:23:31', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'cb53a4c2-df4d-423e-8c9a-0baef2f91e3d' User entered 'No (N)'	System	15 Nov 2020 03:23:36
	System	15 Nov 2020 03:23:36

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:16:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-14T20:23:34', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'cb53a4c2-df4d-423e-8c9a-0baef2f91e3d' User entered '14 Nov 2020 20:23'	System	15 Nov 2020 03:23:36
	System	15 Nov 2020 03:23:36

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:16:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '14 Nov 2020 12:00'	System	12 Nov 2020 18:06:20

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 08:16:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '15 Nov 2020 11:59'	System	12 Nov 2020 18:06:20

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
Data entry locked.	System	12 Nov 2020 18:06:20
User entered 'Day 4'	System	12 Nov 2020 18:06:20

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:16:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-16T06:15:00', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'c52ca792-7672-470f-9b42-b7e54dff027e' User entered 'None (0)'	System	16 Nov 2020 13:15:17
	System	16 Nov 2020 13:15:17

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:16:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-16T06:15:01', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'c52ca792-7672-470f-9b42-b7e54dff027e'	System	16 Nov 2020 13:15:17
User entered 'None (0)'	System	16 Nov 2020 13:15:17

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:16:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-16T06:15:03', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'c52ca792-7672-470f-9b42-b7e54dff027e'	System	16 Nov 2020 13:15:17
User entered 'None (0)'	System	16 Nov 2020 13:15:17

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:16:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-16T06:15:05', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'c52ca792-7672-470f-9b42-b7e54dfc27e' User entered 'None (0)'	System	16 Nov 2020 13:15:17
	System	16 Nov 2020 13:15:17

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:16:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-16T06:15:07', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'c52ca792-7672-470f-9b42-b7e54dff027e'	System	16 Nov 2020 13:15:17
User entered 'None (0)'	System	16 Nov 2020 13:15:17

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:16:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-16T06:15:09', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'c52ca792-7672-470f-9b42-b7e54dff027e' User entered 'None (0)'	System	16 Nov 2020 13:15:17
	System	16 Nov 2020 13:15:17

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:16:08

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 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-16T06:15:12', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'c52ca792-7672-470f-9b42-b7e54dfc27e'	System	16 Nov 2020 13:15:17
User entered 'No (N)'	System	16 Nov 2020 13:15:17

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:16:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-16T06:15:15', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'c52ca792-7672-470f-9b42-b7e54dff027e'	System	16 Nov 2020 13:15:17
User entered '16 Nov 2020 06:15'	System	16 Nov 2020 13:15:17

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:16:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '15 Nov 2020 12:00'	System	12 Nov 2020 18:06:20

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 08:16:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '16 Nov 2020 11:59'	System	12 Nov 2020 18:06:20

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
Data entry locked.	System	12 Nov 2020 18:06:20
User entered 'Day 5'	System	12 Nov 2020 18:06:20

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:16:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-16T23:02:50', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '7a443cfc-ffc8-44c7-b14d-a235a2cecb23'	System	17 Nov 2020 06:03:12
User entered 'None (0)'	System	17 Nov 2020 06:03:12

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:16:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-16T23:02:53', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '7a443cfc-ffc8-44c7-b14d-a235a2cecb23'	System	17 Nov 2020 06:03:12
User entered 'None (0)'	System	17 Nov 2020 06:03:12

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:16:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-16T23:02:55', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '7a443cfc-ffc8-44c7-b14d-a235a2cecb23'	System	17 Nov 2020 06:03:12
User entered 'None (0)'	System	17 Nov 2020 06:03:12

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:16:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-16T23:02:57', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '7a443cfc-ffc8-44c7-b14d-a235a2cecb23' User entered 'None (0)'	System	17 Nov 2020 06:03:12
	System	17 Nov 2020 06:03:12

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:16:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-16T23:03:00', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '7a443cfc-ffc8-44c7-b14d-a235a2cecb23'	System	17 Nov 2020 06:03:12
User entered 'None (0)'	System	17 Nov 2020 06:03:12

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:16:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-16T23:03:02', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '7a443cfc-ffc8-44c7-b14d-a235a2cecb23'	System	17 Nov 2020 06:03:12
User entered 'None (0)'	System	17 Nov 2020 06:03:12

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:16:08

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 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-16T23:03:05', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '7a443cfc-ffc8-44c7-b14d-a235a2cecb23'	System	17 Nov 2020 06:03:12
User entered 'No (N)'	System	17 Nov 2020 06:03:12

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:16:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-16T23:03:09', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '7a443cfc-ffc8-44c7-b14d-a235a2cecb23'	System	17 Nov 2020 06:03:12
User entered '16 Nov 2020 23:03'	System	17 Nov 2020 06:03:12

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:16:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '16 Nov 2020 12:00'	System	12 Nov 2020 18:06:20

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 08:16:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '17 Nov 2020 11:59'	System	12 Nov 2020 18:06:20

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
Data entry locked.	System	12 Nov 2020 18:06:20
User entered 'Day 6'	System	12 Nov 2020 18:06:20

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:16:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-18T05:59:47', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '863c3f68-4fa0-4cf3-b500-1fe42bc5bb70'	System	18 Nov 2020 13:00:04
User entered 'None (0)'	System	18 Nov 2020 13:00:04

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:16:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-18T05:59:49', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '863c3f68-4fa0-4cf3-b500-1fe42bc5bb70' User entered 'None (0)'	System	18 Nov 2020 13:00:04
	System	18 Nov 2020 13:00:04

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:16:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-18T05:59:51', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '863c3f68-4fa0-4cf3-b500-1fe42bc5bb70'	System	18 Nov 2020 13:00:04
User entered 'None (0)'	System	18 Nov 2020 13:00:04

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:16:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-18T05:59:53', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '863c3f68-4fa0-4cf3-b500-1fe42bc5bb70'	System	18 Nov 2020 13:00:04
User entered 'None (0)'	System	18 Nov 2020 13:00:04

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:16:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-18T05:59:55', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '863c3f68-4fa0-4cf3-b500-1fe42bc5bb70' User entered 'None (0)'	System	18 Nov 2020 13:00:04
	System	18 Nov 2020 13:00:04

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:16:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-18T05:59:58', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '863c3f68-4fa0-4cf3-b500-1fe42bc5bb70'	System	18 Nov 2020 13:00:04
User entered 'None (0)'	System	18 Nov 2020 13:00:04

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:16:08

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 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-18T06:00:00', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '863c3f68-4fa0-4cf3-b500-1fe42bc5bb70'	System	18 Nov 2020 13:00:04
User entered 'No (N)'	System	18 Nov 2020 13:00:04

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:16:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-18T06:00:03', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '863c3f68-4fa0-4cf3-b500-1fe42bc5bb70'	System	18 Nov 2020 13:00:04
User entered '18 Nov 2020 06:00'	System	18 Nov 2020 13:00:04

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:16:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '17 Nov 2020 12:00'	System	12 Nov 2020 18:06:20

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 08:16:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '18 Nov 2020 11:59'	System	12 Nov 2020 18:06:20

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
Data entry locked.	System	12 Nov 2020 18:06:20
User entered 'Day 7'	System	12 Nov 2020 18:06:20

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:16:08

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-18T12:20:35', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'ebce8fb2-78a8-410c-89ee-0013f4ed2073'	System	18 Nov 2020 19:20:50
User entered 'None (0)'	System	18 Nov 2020 19:20:50

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:16:08

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-18T12:20:36', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'ebce8fb2-78a8-410c-89ee-0013f4ed2073'	System	18 Nov 2020 19:20:50
User entered 'None (0)'	System	18 Nov 2020 19:20:50

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:16:08

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-18T12:20:38', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'ebce8fb2-78a8-410c-89ee-0013f4ed2073'	System	18 Nov 2020 19:20:50
User entered 'None (0)'	System	18 Nov 2020 19:20:50

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:16:08

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-18T12:20:40', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'ebce8fb2-78a8-410c-89ee-0013f4ed2073'	System	18 Nov 2020 19:20:50
User entered 'None (0)'	System	18 Nov 2020 19:20:50

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:16:08

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-18T12:20:41', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'ebce8fb2-78a8-410c-89ee-0013f4ed2073'	System	18 Nov 2020 19:20:50
User entered 'None (0)'	System	18 Nov 2020 19:20:50

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:16:08

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-18T12:20:43', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'ebce8fb2-78a8-410c-89ee-0013f4ed2073' User entered 'None (0)'	System	18 Nov 2020 19:20:50
	System	18 Nov 2020 19:20:50

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:16:08

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 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-18T12:20:45', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'ebce8fb2-78a8-410c-89ee-0013f4ed2073'	System	18 Nov 2020 19:20:50
User entered 'No (N)'	System	18 Nov 2020 19:20:50

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:16:08

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-11-18T12:20:48', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'ebce8fb2-78a8-410c-89ee-0013f4ed2073' User entered '18 Nov 2020 12:20'	System	18 Nov 2020 19:20:50
	System	18 Nov 2020 19:20:50

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:16:08

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '18 Nov 2020 12:00'	System	12 Nov 2020 18:06:20

US3562229

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 08:16:08

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:47:36
User entered '19 Nov 2020 11:59'	System	12 Nov 2020 18:06:20

US3562229

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Nov 2020 22:36:32

US3562229

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered '19 Nov 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Nov 2020 22:36:32

US3562229

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Nov 2020 22:36:32

US3562229

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Nov 2020 22:36:32

US3562229

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Nov 2020 22:36:38

US3562229

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User entered 'l'	System	19 Nov 2020 22:36:38

US3562229

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	01 Dec 2020 13:58:40

US3562229

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:08

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4) (b) (4)	10 Mar 2021 16:44:41
User closed query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	02 Dec 2020 06:26:08
Query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'confirmed as it is' (Site from System).	Dhwani Shah (b) (4) (b) (4)	01 Dec 2020 13:58:49
User opened query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	01 Dec 2020 13:58:40
User entered '25 Nov 2020'	Dhwani Shah (b) (4) (b) (4)	01 Dec 2020 13:58:40

US3562229

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	01 Dec 2020 13:58:40

US3562229

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	01 Dec 2020 13:58:40

US3562229

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	01 Dec 2020 13:58:56

US3562229

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User entered 'l'	System	01 Dec 2020 13:58:56

US3562229

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	04 Dec 2020 18:40:09

US3562229

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered '3 Dec 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	04 Dec 2020 18:40:09

US3562229

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	04 Dec 2020 18:40:09

US3562229

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	04 Dec 2020 18:40:09

US3562229

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	04 Dec 2020 18:40:14

US3562229

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User entered 'l'	System	04 Dec 2020 18:40:14

US3562229

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:16:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:04:03
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 23:39:10

US3562229

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:04:03
User entered '10 Dec 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 23:39:10

US3562229

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:04:03
User entered 'Clinic (Clinic)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 23:39:10

US3562229

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:16:08

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User entered 'VISIT3'	System	15 Dec 2020 23:39:10

US3562229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:04:03
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 23:39:34

US3562229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:04:03
User entered '10 Dec 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 23:39:34

US3562229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:04:03
User entered '09:55'	(b) (4) Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 23:39:34

US3562229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User entered '10 Dec 2020 09:55'	System	15 Dec 2020 23:39:34

US3562229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:04:03
User entered '97.9' F	(b) (4) Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 23:39:34

US3562229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:04:03
User entered 'Oral (Oral)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 23:39:34

US3562229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:04:03
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 23:39:34

US3562229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:04:03
User entered '80'	(b) (4) Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 23:39:34

US3562229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User entered 'bpm'	System	15 Dec 2020 23:39:34

US3562229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:04:03
User entered '14'	(b) (4) Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 23:39:34

US3562229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User entered 'breaths/min'	System	15 Dec 2020 23:39:34

US3562229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:04:03
User entered '130'	(b) (4) Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 23:39:34

US3562229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User entered 'mmHg'	System	15 Dec 2020 23:39:34

US3562229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:04:03
User entered '86'	(b) (4) Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 23:39:34

US3562229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:08

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User entered 'mmHg'	System	15 Dec 2020 23:39:34

US3562229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:08

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37

US3562229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:08

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37

US3562229

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:16:08

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:04:03
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 23:39:41

US3562229

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:16:08

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:04:03
User entered '10 Dec 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 23:39:41

US3562229

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:16:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:04:03
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 23:39:54

US3562229

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:16:08

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:04:03
User entered '10 Dec 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 23:39:54

US3562229

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:16:08

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:04:03
User entered '10:04'	(b) (4) Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 23:39:54

US3562229

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User entered '10 Dec 2020 10:04'	System	15 Dec 2020 23:39:54

US3562229

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	12 Mar 2021 22:04:03
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	15 Dec 2020 23:38:56

US3562229

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User entered 'l'	System	15 Dec 2020 23:38:56

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[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 (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-12-15T04:39:49', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'f1fb86ea-e4ca-433c-a351-a2b937c45ade' User entered 'No (N)'	System	15 Dec 2020 11:40:01
	System	15 Dec 2020 11:40:01

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

Have you been exposed to someone with 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 (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-12-15T04:39:55', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'f1fb86ea-e4ca-433c-a351-a2b937c45ade'	System	15 Dec 2020 11:40:01
User entered 'No (N)'	System	15 Dec 2020 11:40:01

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-12-15T04:39:59', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'f1fb86ea-e4ca-433c-a351-a2b937c45ade' User entered '15 Dec 2020 04:39:59'	System	15 Dec 2020 11:40:01
	System	15 Dec 2020 11:40:01

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[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 (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-12-21T08:57:39', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '30444db3-7cca-40b4-8980-2884a6ded5d2' User entered 'No (N)'	System	21 Dec 2020 15:57:52
	System	21 Dec 2020 15:57:52

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

Have you been exposed to someone with 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 (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-12-21T08:57:46', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '30444db3-7cca-40b4-8980-2884a6ded5d2'	System	21 Dec 2020 15:57:52
User entered 'No (N)'	System	21 Dec 2020 15:57:52

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-12-21T08:57:49', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '30444db3-7cca-40b4-8980-2884a6ded5d2'	System	21 Dec 2020 15:57:52
User entered '21 Dec 2020 08:57:49'	System	21 Dec 2020 15:57:52

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[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 (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-12-29T18:12:48', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'e637d5d6-e52f-4495-a8b8-a38fc26cb843' User entered 'No (N)'	System	30 Dec 2020 01:13:00
	System	30 Dec 2020 01:13:00

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

Have you been exposed to someone with 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 (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-12-29T18:12:53', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'e637d5d6-e52f-4495-a8b8-a38fc26cb843'	System	30 Dec 2020 01:13:00
User entered 'No (N)'	System	30 Dec 2020 01:13:00

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2020-12-29T18:12:57', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'e637d5d6-e52f-4495-a8b8-a38fc26cb843' User entered '29 Dec 2020 18:12:57'	System	30 Dec 2020 01:13:00
	System	30 Dec 2020 01:13:00

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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 (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2021-01-03T18:16:14', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'fe17c9e2-ce9f-4a0d-9a52-5dccf191495e'	System	04 Jan 2021 01:16:31
User entered 'No (N)'	System	04 Jan 2021 01:16:31

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

Have you been exposed to someone with 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 (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2021-01-03T18:16:25', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'fe17c9e2-ce9f-4a0d-9a52-5dccb191495e'	System	04 Jan 2021 01:16:31
User entered 'No (N)'	System	04 Jan 2021 01:16:31

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2021-01-03T18:16:28', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'fe17c9e2-ce9f-4a0d-9a52-5dccb191495e' User entered '03 Jan 2021 18:16:28'	System	04 Jan 2021 01:16:31
	System	04 Jan 2021 01:16:31

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[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 (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2021-01-12T12:15:41', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '2e36064a-7e67-4051-aa34-5c8c9b879d01'	System	12 Jan 2021 19:15:53
User entered 'No (N)'	System	12 Jan 2021 19:15:53

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

Have you been exposed to someone with 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 (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2021-01-12T12:15:44', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '2e36064a-7e67-4051-aa34-5c8c9b879d01'	System	12 Jan 2021 19:15:53
User entered 'No (N)'	System	12 Jan 2021 19:15:53

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2021-01-12T12:15:48', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '2e36064a-7e67-4051-aa34-5c8c9b879d01' User entered '12 Jan 2021 12:15:48'	System	12 Jan 2021 19:15:53
	System	12 Jan 2021 19:15:53

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[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 (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2021-01-17T10:36:26', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'aab08d97-8746-46a4-9547-399142689914' User entered 'No (N)'	System	17 Jan 2021 17:36:46
	System	17 Jan 2021 17:36:46

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

Have you been exposed to someone with 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 (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2021-01-17T10:36:42', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'aab08d97-8746-46a4-9547-399142689914' User entered 'No (N)'	System	17 Jan 2021 17:36:46
	System	17 Jan 2021 17:36:46

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2021-01-17T10:36:45', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'aab08d97-8746-46a4-9547-399142689914' User entered '17 Jan 2021 10:36:45'	System	17 Jan 2021 17:36:46
	System	17 Jan 2021 17:36:46

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[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 (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2021-01-25T07:22:40', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '0d70672b-96f3-4095-9a54-da78393fa5ca' User entered 'No (N)'	System	25 Jan 2021 14:22:54

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

Have you been exposed to someone with 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 (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2021-01-25T07:22:49', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '0d70672b-96f3-4095-9a54-da78393fa5ca' User entered 'No (N)'	System	25 Jan 2021 14:22:54

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2021-01-25T07:22:52', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '0d70672b-96f3-4095-9a54-da78393fa5ca' User entered '25 Jan 2021 07:22:52'	System	25 Jan 2021 14:22:54
	System	25 Jan 2021 14:22:54

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[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 (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2021-02-02T16:46:39', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '3cdd7060-90a9-4227-9af0-0d6db06c7a4c'	System	02 Feb 2021 23:46:57
User entered 'No (N)'	System	02 Feb 2021 23:46:57

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

Have you been exposed to someone with 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 (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2021-02-02T16:46:51', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '3cdd7060-90a9-4227-9af0-0d6db06c7a4c'	System	02 Feb 2021 23:46:57
User entered 'No (N)'	System	02 Feb 2021 23:46:57

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2021-02-02T16:46:54', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '3cdd7060-90a9-4227-9af0-0d6db06c7a4c'	System	02 Feb 2021 23:46:57
User entered '02 Feb 2021 16:46:54'	System	02 Feb 2021 23:46:57

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[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 (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2021-02-07T11:31:03', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '16aaa96f-6650-4eed-a210-c0b7129a9903'	System	07 Feb 2021 18:31:17
User entered 'No (N)'	System	07 Feb 2021 18:31:17

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

Have you been exposed to someone with 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 (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2021-02-07T11:31:13', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '16aaa96f-6650-4eed-a210-c0b7129a9903'	System	07 Feb 2021 18:31:17
User entered 'No (N)'	System	07 Feb 2021 18:31:17

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2021-02-07T11:31:16', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '16aaa96f-6650-4eed-a210-c0b7129a9903'	System	07 Feb 2021 18:31:17
User entered '07 Feb 2021 11:31:16'	System	07 Feb 2021 18:31:17

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[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 (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2021-02-15T11:29:51', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'c0396e81-d4c3-48a3-b5b2-0dbe64132b52'	System	15 Feb 2021 18:30:08
User entered 'No (N)'	System	15 Feb 2021 18:30:08

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

Have you been exposed to someone with 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 (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2021-02-15T11:29:56', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'c0396e81-d4c3-48a3-b5b2-0dbe64132b52'	System	15 Feb 2021 18:30:08
User entered 'No (N)'	System	15 Feb 2021 18:30:08

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2021-02-15T11:30:04', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'c0396e81-d4c3-48a3-b5b2-0dbe64132b52'	System	15 Feb 2021 18:30:08
User entered '15 Feb 2021 11:30:04'	System	15 Feb 2021 18:30:08

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[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 (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2021-03-01T12:00:43-07:00', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'fff39dcc-b076-46e6-b1f7-273dec79142f' User entered 'No (N)'	System	01 Mar 2021 19:00:57
	System	01 Mar 2021 19:00:57

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

Have you been exposed to someone with 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 (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2021-03-01T12:00:45-07:00', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'fff39dcc-b076-46e6-b1f7-273dec79142f'	System	01 Mar 2021 19:00:57
User entered 'No (N)'	System	01 Mar 2021 19:00:57

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2021-03-01T12:00:48-07:00', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'fff39dcc-b076-46e6-b1f7-273dec79142f' User entered '01 Mar 2021 12:00:48'	System	01 Mar 2021 19:00:57
	System	01 Mar 2021 19:00:57

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[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 (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2021-03-07T19:11:04-07:00', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '2903a1a1-a808-4bb2-812b-c29fd499b1bd'	System	08 Mar 2021 02:20:03
User entered 'No (N)'	System	08 Mar 2021 02:20:03

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

Have you been exposed to someone with 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 (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2021-03-07T19:11:06-07:00', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '2903a1a1-a808-4bb2-812b-c29fd499b1bd'	System	08 Mar 2021 02:20:03
User entered 'No (N)'	System	08 Mar 2021 02:20:03

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2021-03-07T19:11:09-07:00', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '2903a1a1-a808-4bb2-812b-c29fd499b1bd' User entered '07 Mar 2021 19:11:09'	System	08 Mar 2021 02:20:03
	System	08 Mar 2021 02:20:03

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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 (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2021-03-16T07:38:24-07:00', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '18f030df-a120-43a7-8292-68e7d0824a62'	System	16 Mar 2021 14:38:32
User entered 'No (N)'	System	16 Mar 2021 14:38:32

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

Have you been exposed to someone with 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 (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2021-03-16T07:38:27-07:00', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '18f030df-a120-43a7-8292-68e7d0824a62'	System	16 Mar 2021 14:38:32
User entered 'No (N)'	System	16 Mar 2021 14:38:32

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2021-03-16T07:38:29-07:00', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '18f030df-a120-43a7-8292-68e7d0824a62'	System	16 Mar 2021 14:38:32
User entered '16 Mar 2021 07:38:29'	System	16 Mar 2021 14:38:32

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[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 (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2021-03-23T19:43:05-07:00', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '90f29a61-d25a-407c-8a12-6e9efaa5149a'	System	24 Mar 2021 02:45:04
User entered 'Yes (Y)'	System	24 Mar 2021 02:45:04

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

Have you been exposed to someone with 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 (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2021-03-23T19:43:12-07:00', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '90f29a61-d25a-407c-8a12-6e9efaa5149a'	System	24 Mar 2021 02:45:04
User entered 'No (N)'	System	24 Mar 2021 02:45:04

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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 (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2021-03-23T19:43:20-07:00', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '90f29a61-d25a-407c-8a12-6e9efaa5149a' User entered 'No (N)'	System	24 Mar 2021 02:45:04
	System	24 Mar 2021 02:45:04

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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 (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2021-03-23T19:44:10-07:00', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '90f29a61-d25a-407c-8a12-6e9efaa5149a'	System	24 Mar 2021 02:45:04
User entered 'Yes (Y)'	System	24 Mar 2021 02:45:04

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2021-03-23T19:44:32-07:00', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '90f29a61-d25a-407c-8a12-6e9efaa5149a'	System	24 Mar 2021 02:45:04
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	24 Mar 2021 02:45:04

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2021-03-23T19:44:43-07:00', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '90f29a61-d25a-407c-8a12-6e9efaa5149a' User entered '23 Mar 2021 19:44:43'	System	24 Mar 2021 02:45:04
	System	24 Mar 2021 02:45:04

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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 (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2021-03-28T11:49:11-07:00', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '2cce7f6b-f516-4f1d-aded-039b4169cd04'	System	28 Mar 2021 18:49:23
User entered 'No (N)'	System	28 Mar 2021 18:49:23

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

Have you been exposed to someone with 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 (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2021-03-28T11:49:15-07:00', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '2cce7f6b-f516-4f1d-aded-039b4169cd04'	System	28 Mar 2021 18:49:23
User entered 'No (N)'	System	28 Mar 2021 18:49:23

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2021-03-28T11:49:20-07:00', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '2cce7f6b-f516-4f1d-aded-039b4169cd04'	System	28 Mar 2021 18:49:23
User entered '28 Mar 2021 11:49:20'	System	28 Mar 2021 18:49:23

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[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 (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2021-04-06T16:57:32-07:00', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '2a8cf89d-3520-41f3-a0f3-33ac99c0b386'	System	06 Apr 2021 23:57:40
User entered 'No (N)'	System	06 Apr 2021 23:57:40

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

Have you been exposed to someone with 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 (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2021-04-06T16:57:35-07:00', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '2a8cf89d-3520-41f3-a0f3-33ac99c0b386'	System	06 Apr 2021 23:57:40
User entered 'No (N)'	System	06 Apr 2021 23:57:40

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2021-04-06T16:57:38-07:00', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '2a8cf89d-3520-41f3-a0f3-33ac99c0b386'	System	06 Apr 2021 23:57:40
User entered '06 Apr 2021 16:57:38'	System	06 Apr 2021 23:57:40

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[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 (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2021-04-20T17:59:24-07:00', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'd0db3a92-a9fe-4dba-8559-0d8fdb342be6'	System	21 Apr 2021 01:00:13
User entered 'Yes (Y)'	System	21 Apr 2021 01:00:13

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

Have you been exposed to someone with 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 (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2021-04-20T17:59:31-07:00', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'd0db3a92-a9fe-4dba-8559-0d8fdb342be6'	System	21 Apr 2021 01:00:13
User entered 'No (N)'	System	21 Apr 2021 01:00:13

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[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 (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2021-04-20T17:59:40-07:00', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'd0db3a92-a9fe-4dba-8559-0d8fdb342be6'	System	21 Apr 2021 01:00:13
User entered 'No (N)'	System	21 Apr 2021 01:00:13

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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 (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2021-04-20T17:59:49-07:00', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'd0db3a92-a9fe-4dba-8559-0d8fdb342be6'	System	21 Apr 2021 01:00:13
User entered 'Yes (Y)'	System	21 Apr 2021 01:00:13

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2021-04-20T17:59:56-07:00', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'd0db3a92-a9fe-4dba-8559-0d8fdb342be6'	System	21 Apr 2021 01:00:13
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	21 Apr 2021 01:00:13

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2021-04-20T17:59:59-07:00', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: 'd0db3a92-a9fe-4dba-8559-0d8fdb342be6'	System	21 Apr 2021 01:00:13
User entered '20 Apr 2021 17:59:59'	System	21 Apr 2021 01:00:13

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[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 (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2021-04-26T12:01:08-07:00', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '850a5ba7-3f05-4f40-958c-f2cac460c9d6'	System	26 Apr 2021 19:01:18
User entered 'No (N)'	System	26 Apr 2021 19:01:18

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

Have you been exposed to someone with 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 (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2021-04-26T12:01:12-07:00', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '850a5ba7-3f05-4f40-958c-f2cac460c9d6'	System	26 Apr 2021 19:01:18
User entered 'No (N)'	System	26 Apr 2021 19:01:18

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2021-04-26T12:01:15-07:00', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '850a5ba7-3f05-4f40-958c-f2cac460c9d6'	System	26 Apr 2021 19:01:18
User entered '26 Apr 2021 12:01:15'	System	26 Apr 2021 19:01:18

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[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 (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2021-05-03T17:53:51-07:00', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '05f6d8ee-7727-4b00-a9f1-2d60cc425b4f'	System	04 May 2021 00:54:02
User entered 'No (N)'	System	04 May 2021 00:54:02

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

Have you been exposed to someone with 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 (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2021-05-03T17:53:54-07:00', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '05f6d8ee-7727-4b00-a9f1-2d60cc425b4f'	System	04 May 2021 00:54:02
User entered 'No (N)'	System	04 May 2021 00:54:02

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2021-05-03T17:53:56-07:00', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '05f6d8ee-7727-4b00-a9f1-2d60cc425b4f' User entered '03 May 2021 17:53:56'	System	04 May 2021 00:54:02
	System	04 May 2021 00:54:02

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '29 Oct 2022 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '02 Nov 2022 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '05 Nov 2022 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '09 Nov 2022 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '12 Nov 2022 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '16 Nov 2022 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '19 Nov 2022 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '23 Nov 2022 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '26 Nov 2022 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '30 Nov 2022 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '03 Dec 2022 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '07 Dec 2022 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '10 Dec 2022 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '14 Dec 2022 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '17 Dec 2022 00:01'	System	20 Nov 2020 12:48:37

US3562229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 08:16:08

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:48:37
Amendment Manager: User entered '21 Dec 2022 23:59'	System	20 Nov 2020 12:48:37

US3562229

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:16:08

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 18:01:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2021-03-01T12:00:30-07:00', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '31c85441-6b33-4d87-95e9-22a8a588a130'	System	01 Mar 2021 19:00:42
User entered 'No (N)'	System	01 Mar 2021 19:00:42

US3562229

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 08:16:08

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:01:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B2FE2865-F9F3-4E8C-8E9E-B48C07312A0D)', Time: '2021-03-01T12:00:35-07:00', User OID: 'PatientReportedOutcome (US3562229)', ODM File OID: '31c85441-6b33-4d87-95e9-22a8a588a130' User entered '01 Mar 2021 12:00:35'	System	01 Mar 2021 19:00:42
	System	01 Mar 2021 19:00:42

US3562229

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4) (b) (4)	10 Mar 2021 16:44:41
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	11 Feb 2021 18:17:07
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	10 Feb 2021 18:36:17
User entered 'No (N)'	Sabrina Bolland (b) (4) (b) (4)	10 Feb 2021 18:36:17

US3562229

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4) (b) (4)	10 Mar 2021 16:44:41
User entered empty.	Sabrina Bolland (b) (4) (b) (4)	10 Feb 2021 18:36:17

US3562229

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered empty; reason for change Data Entry Error	(b) (4) Dhwani Shah (b) (4)	11 Feb 2021 18:17:07
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) Sabrina Bolland (b) (4)	10 Feb 2021 18:36:17

US3562229

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4) (b) (4)	10 Mar 2021 16:44:41
User closed query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided. Please review and reconcile.' (Site from System).	System	11 Feb 2021 18:17:07
User opened query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided. Please review and reconcile.' (Site from System).	System	10 Feb 2021 18:36:17
User entered empty.	Sabrina Bolland (b) (4) (b) (4)	10 Feb 2021 18:36:17

US3562229

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User signature succeeded.	Joseph Davis (b) (4)	10 Mar 2021 16:44:41
User entered 'Yes (Y)'	(b) (4) Sabrina Bolland (b) (4)	10 Feb 2021 18:36:23

US3562229

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 05:28:37
User entered 'l'	System	10 Feb 2021 18:36:23

US3562229

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:22:09
User signature succeeded.	Joseph Davis (b) (4) (b) (4)	11 Mar 2021 17:36:25
User entered 'Yes (Y)'	Sabrina Bolland (b) (4) (b) (4)	10 Feb 2021 18:37:08

US3562229

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:22:09
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered '10 Feb 2021'	(b) (4) Sabrina Bolland (b) (4) (b) (4)	10 Feb 2021 18:37:08

US3562229

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:22:09
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sabrina Bolland (b) (4)	10 Feb 2021 18:37:08

US3562229

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:22:09
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered empty.	(b) (4) Sabrina Bolland (b) (4) (b) (4)	10 Feb 2021 18:37:08

US3562229

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:22:09
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered 'Yes (Y)'	(b) (4) Sabrina Bolland (b) (4)	10 Feb 2021 18:37:20

US3562229

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:22:09
User entered 'l'	System	10 Feb 2021 18:37:20

US3562229

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:22:09
User signature succeeded.	Joseph Davis (b) (4)	02 Apr 2021 14:10:35
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 14:24:21

US3562229

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:22:09
User signature succeeded.	Joseph Davis (b) (4)	02 Apr 2021 14:10:35
User entered '11 Mar 2021'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 14:24:21

US3562229

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:22:09
User signature succeeded.	Joseph Davis (b) (4)	02 Apr 2021 14:10:35
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 14:24:21

US3562229

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:22:09
User signature succeeded.	Joseph Davis (b) (4)	02 Apr 2021 14:10:35
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 14:24:21

US3562229

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:22:09
User signature succeeded.	Joseph Davis (b) (4)	02 Apr 2021 14:10:35
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 14:24:26

US3562229

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:22:09
User entered 'l'	System	29 Mar 2021 14:24:26

US3562229

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	16 Apr 2021 20:01:54
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	13 Apr 2021 20:39:34

US3562229

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	16 Apr 2021 20:01:54
User entered '9 Apr 2021'	(b) (4) Dhwani Shah (b) (4) (b) (4)	13 Apr 2021 20:39:34

US3562229

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	16 Apr 2021 20:01:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	13 Apr 2021 20:39:34

US3562229

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	16 Apr 2021 20:01:54
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	13 Apr 2021 20:39:34

US3562229

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	16 Apr 2021 20:01:54
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	13 Apr 2021 20:39:38

US3562229

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:08

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 20:39:38

US3562229

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

Form: Visit Date

Generated On: 10 Jun 2021 08:16:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Jan 2021 20:24:51

US3562229

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

Form: Visit Date

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered '12 Jan 2021'	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Jan 2021 20:24:51

US3562229

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

Form: Visit Date

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered 'Clinic (Clinic)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Jan 2021 20:24:51

US3562229

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

Form: Visit Date

Generated On: 10 Jun 2021 08:16:08

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User entered 'UNBLND_DECIDE'	System	12 Jan 2021 20:24:51

US3562229

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

Form: Unblinding

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered '12 Jan 2021'	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Jan 2021 20:25:06

US3562229

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

Form: Unblinding

Generated On: 10 Jun 2021 08:16:08

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered '0'	(b) (4) Dhwani Shah (b) (4)	08 Apr 2021 21:47:29
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 15:35:06

US3562229

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

Form: Unblinding

Generated On: 10 Jun 2021 08:16:08

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Jan 2021 20:25:06

US3562229

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

Form: Unblinding

Generated On: 10 Jun 2021 08:16:08

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User closed query 'Per IRT: The subject was unblinded under A5 but "Under what version of the Protocol was the Participant unblinded? is blank". Please review and reconcile.' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	12 Apr 2021 05:56:20
Query 'Per IRT: The subject was unblinded under A5 but "Under what version of the Protocol was the Participant unblinded? is blank". Please review and reconcile.' answered with 'updated' (Site from DM). User entered 'Amendment 5 (Amendment 5)'	Joseph Davis (b) (4) (b) (4)	08 Apr 2021 22:10:23
User opened query 'Per IRT: The subject was unblinded under A5 but "Under what version of the Protocol was the Participant unblinded? is blank". Please review and reconcile.' (Site from DM). Amendment Manager inserted this DataPoint.	Dhwani Shah (b) (4) (b) (4)	08 Apr 2021 21:47:54
	Dhwani Shah (b) (4) (b) (4)	08 Apr 2021 21:47:29
	(b) (4), (b) (6)	08 Apr 2021 06:40:34
	System	06 Mar 2021 15:35:06

US3562229

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

Form: Unblinding

Generated On: 10 Jun 2021 08:16:08

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User closed query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Apr 2021 04:57:03
User closed query 'Per IRT, subject was unblinded on 30DEC2020. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 05:56:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
Query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' answered with 'pt was unblinded over the phone under amendment 5 and then pt return to site for OLD1 and sign consent on 12Jan2021 prior to any study procedure. Confirmed as it is ! No changes required ' (Site from System).	Dhwani Shah (b) (4)	08 Apr 2021 21:49:34
Query 'Per IRT, subject was unblinded on 30DEC2020. Please review and reconcile.' answered with 'updated' (Site from DM).	Dhwani Shah (b) (4)	08 Apr 2021 21:48:16
User opened query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	System	08 Apr 2021 21:47:29
User entered '30 Dec 2020' reason for change: Data Entry Error	Dhwani Shah (b) (4)	08 Apr 2021 21:47:29
User opened query 'Per IRT, subject was unblinded on 30DEC2020. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 11:05:00
User entered '12 Jan 2021'	Dhwani Shah (b) (4)	12 Jan 2021 20:25:06

US3562229

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

Form: Unblinding

Generated On: 10 Jun 2021 08:16:08

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered 'Placebo (Placebo)' reason for change: Data Entry Error	(b) (4) Dhwani Shah (b) (4)	12 Jan 2021 20:25:21
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Dhwani Shah (b) (4)	12 Jan 2021 20:25:06

US3562229

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

Form: Unblinding

Generated On: 10 Jun 2021 08:16:08

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4) (b) (4)	08 Apr 2021 22:10:23
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 09:59:41
User entered 'Placebo (Placebo)' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	12 Jan 2021 20:25:21
User entered 'mRNA-1273 (mRNA-1273)'	Dhwani Shah (b) (4) (b) (4)	12 Jan 2021 20:25:06

US3562229

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

Form: Unblinding

Generated On: 10 Jun 2021 08:16:08

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4) (b) (4)	08 Apr 2021 22:10:23
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 09:59:41
User entered 'Placebo (Placebo)' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	12 Jan 2021 20:25:21
User entered 'mRNA-1273 (mRNA-1273)'	Dhwani Shah (b) (4) (b) (4)	12 Jan 2021 20:25:06

US3562229

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

Form: Unblinding

Generated On: 10 Jun 2021 08:16:08

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4) (b) (4)	08 Apr 2021 22:10:23
User closed query 'Actual dose 1 and Actual dose 2 are both recorded as mRNA-1273, however, 'Will participant receive mRNA-1273?' is Yes. Please reconcile.' (Site from System).	System	12 Jan 2021 20:25:21
Query 'Actual dose 1 and Actual dose 2 are both recorded as mRNA-1273, however, 'Will participant receive mRNA-1273?' is Yes. Please reconcile.' answered by data change (Site from System).	System	12 Jan 2021 20:25:21
User opened query 'Actual dose 1 and Actual dose 2 are both recorded as mRNA-1273, however, 'Will participant receive mRNA-1273?' is Yes. Please reconcile.' (Site from System).	System	12 Jan 2021 20:25:06
User entered 'Yes (Y)'	Dhwani Shah (b) (4) (b) (4)	12 Jan 2021 20:25:06

US3562229

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

Form: Unblinding

Generated On: 10 Jun 2021 08:16:08

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User entered '1'	System	12 Jan 2021 20:25:21
User entered empty.	System	12 Jan 2021 20:25:06

US3562229

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

Form: Unblinding

Generated On: 10 Jun 2021 08:16:08

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User entered 'l'	System	12 Jan 2021 20:25:21
User entered empty.	System	12 Jan 2021 20:25:06

US3562229

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:16:08

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered missing code ND - Not Done.	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Jan 2021 20:26:26

US3562229

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:16:08

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered missing code ND - Not Done.	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Jan 2021 20:26:26

US3562229

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:16:08

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User entered empty.	System	12 Jan 2021 20:26:26
DataPoint set to visible.	System	12 Jan 2021 20:25:21

US3562229

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:16:08

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered missing code ND - Not Done.	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Jan 2021 20:26:26

US3562229

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:16:08

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered missing code ND - Not Done.	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Jan 2021 20:26:26

US3562229

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:16:08

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User entered empty.	System	12 Jan 2021 20:26:26
DataPoint set to visible.	System	12 Jan 2021 20:25:21

US3562229

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:08

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User accepted default value 'Pre-Dose (PREDOSE)'	Dhwani Shah (b) (4) (b) (4)	12 Jan 2021 20:26:26

US3562229

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Jan 2021 20:26:26

US3562229

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:08

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered '12 Jan 2021'	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Jan 2021 20:26:26

US3562229

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered '10:11'	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Jan 2021 20:26:26

US3562229

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User entered '12 Jan 2021 10:11'	System	12 Jan 2021 20:26:26

US3562229

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered '97.9' F	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Jan 2021 20:26:26

US3562229

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered 'Oral (Oral)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Jan 2021 20:26:26

US3562229

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Jan 2021 20:26:26

US3562229

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered '76'	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Jan 2021 20:26:26

US3562229

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User entered 'bpm'	System	12 Jan 2021 20:26:26

US3562229

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered '16'	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Jan 2021 20:26:26

US3562229

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User entered 'breaths/min'	System	12 Jan 2021 20:26:26

US3562229

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered '145'	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Jan 2021 20:26:26

US3562229

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User entered 'mmHg'	System	12 Jan 2021 20:26:26

US3562229

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered '90'	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Jan 2021 20:26:26

US3562229

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:08

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User entered 'mmHg'	System	12 Jan 2021 20:26:26

US3562229

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:16:08

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered missing code ND - Not Done.	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Jan 2021 20:26:26

US3562229

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:16:08

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered missing code ND - Not Done.	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Jan 2021 20:26:26

US3562229

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 08:16:08

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User entered empty.	System	12 Jan 2021 20:26:26
DataPoint set to visible.	System	12 Jan 2021 20:25:21

US3562229

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:08

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User accepted default value 'Post-Dose (POSTDOSE)'	Dhwani Shah (b) (4) (b) (4)	12 Jan 2021 20:26:26

US3562229

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Jan 2021 20:26:26

US3562229

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:08

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered '12 Jan 2021'	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Jan 2021 20:26:26

US3562229

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered '11:18'	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Jan 2021 20:26:26

US3562229

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User entered '12 Jan 2021 11:18'	System	12 Jan 2021 20:26:26

US3562229

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered '97.9' F	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Jan 2021 20:26:26

US3562229

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered 'Oral (Oral)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Jan 2021 20:26:26

US3562229

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Jan 2021 20:26:26

US3562229

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered '64'	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Jan 2021 20:26:26

US3562229

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User entered 'bpm'	System	12 Jan 2021 20:26:26

US3562229

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered '16'	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Jan 2021 20:26:26

US3562229

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User entered 'breaths/min'	System	12 Jan 2021 20:26:26

US3562229

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered '130'	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Jan 2021 20:26:26

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User entered 'mmHg'	System	12 Jan 2021 20:26:26

US3562229

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered '85'	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Jan 2021 20:26:26

US3562229

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:08

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User entered 'mmHg'	System	12 Jan 2021 20:26:26

US3562229

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

Form: Physical Examination

Generated On: 10 Jun 2021 08:16:08

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Jan 2021 20:25:30

US3562229

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

Form: Physical Examination

Generated On: 10 Jun 2021 08:16:08

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered '12 Jan 2021'	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Jan 2021 20:25:30

US3562229

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

Form: Exposure

Generated On: 10 Jun 2021 08:16:08

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Jan 2021 20:26:47

US3562229

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

Form: Exposure

Generated On: 10 Jun 2021 08:16:08

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Jan 2021 20:26:47

US3562229

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

Form: Exposure

Generated On: 10 Jun 2021 08:16:08

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 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Jan 2021 20:26:47

US3562229

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

Form: Exposure

Generated On: 10 Jun 2021 08:16:08

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User entered 'mRNA-1273'	System	12 Jan 2021 20:26:47
DataPoint set to visible.	System	12 Jan 2021 20:25:21

US3562229

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

Form: Exposure

Generated On: 10 Jun 2021 08:16:08

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered '12 Jan 2021'	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Jan 2021 20:26:47

US3562229

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

Form: Exposure

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered '10:48'	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Jan 2021 20:26:47

US3562229

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

Form: Exposure

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User entered '12 Jan 2021 10:48'	System	12 Jan 2021 20:26:47

US3562229

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

Form: Exposure

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered 'Left Arm (LEFT ARM)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Jan 2021 20:26:47

US3562229

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

Form: Exposure

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User entered 'ONCE'	System	12 Jan 2021 20:26:47

US3562229

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

Form: Exposure

Generated On: 10 Jun 2021 08:16:08

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User entered 'INTRAMUSCULAR'	System	12 Jan 2021 20:26:47

US3562229

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:16:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Jan 2021 20:24:22

US3562229

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:16:08

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered '12 Jan 2021'	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Jan 2021 20:24:22

US3562229

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:16:08

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered '10:20'	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Jan 2021 20:24:22

US3562229

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User entered '12 Jan 2021 10:20'	System	12 Jan 2021 20:24:22

US3562229

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:16:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Jan 2021 20:24:35

US3562229

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:16:08

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered '12 Jan 2021'	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Jan 2021 20:24:35

US3562229

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:16:08

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered '10:15'	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Jan 2021 20:24:35

US3562229

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User entered '12 Jan 2021 10:15'	System	12 Jan 2021 20:24:35

US3562229

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

Form: Continuing

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Jan 2021 20:25:36

US3562229

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

Form: Continuing

Generated On: 10 Jun 2021 08:16:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User entered 'l'	System	12 Jan 2021 20:25:36

US3562229

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered 'Yes (Y)'	(b) (4) Sabrina Bolland (b) (4) (b) (4)	19 Jan 2021 17:09:26

US3562229

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered '19 Jan 2021'	(b) (4) Sabrina Bolland (b) (4) (b) (4)	19 Jan 2021 17:09:26

US3562229

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sabrina Bolland (b) (4) (b) (4)	19 Jan 2021 17:09:26

US3562229

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered empty.	(b) (4) Sabrina Bolland (b) (4) (b) (4)	19 Jan 2021 17:09:26

US3562229

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered 'Yes (Y)'	(b) (4) Sabrina Bolland (b) (4) (b) (4)	19 Jan 2021 17:09:32

US3562229

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User entered 'l'	System	19 Jan 2021 17:09:32

US3562229

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:08

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User entered '1'	System	19 Jan 2021 17:09:32
DataPoint set to visible.	System	19 Jan 2021 17:09:32

US3562229

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:16:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:23:14
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	11 Feb 2021 19:38:10

US3562229

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:23:14
User entered '11 Feb 2021'	(b) (4) Dhwani Shah (b) (4) (b) (4)	11 Feb 2021 19:38:10

US3562229

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:23:14
User entered 'Clinic (Clinic)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	11 Feb 2021 19:38:10

US3562229

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:16:08

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User entered 'OLD29'	System	11 Feb 2021 19:38:10

US3562229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:08

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User accepted default value 'Pre-Dose (PREDOSE)'	Dhwani Shah (b) (4) (b) (4)	11 Feb 2021 19:38:56

US3562229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:23:14
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	11 Feb 2021 19:38:56

US3562229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:23:14
User entered '11 Feb 2021'	(b) (4) Dhwani Shah (b) (4) (b) (4)	11 Feb 2021 19:38:56

US3562229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:23:14
User entered '09:55'	(b) (4) Dhwani Shah (b) (4) (b) (4)	11 Feb 2021 19:38:56

US3562229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User entered '11 Feb 2021 09:55'	System	11 Feb 2021 19:38:56

US3562229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:23:14
User entered '97.9' F	(b) (4) Dhwani Shah (b) (4) (b) (4)	11 Feb 2021 19:38:56

US3562229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:23:14
User entered 'Oral (Oral)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	11 Feb 2021 19:38:56

US3562229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:23:14
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	11 Feb 2021 19:38:56

US3562229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:23:14
User entered '60'	(b) (4) Dhwani Shah (b) (4) (b) (4)	11 Feb 2021 19:38:56

US3562229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User entered 'bpm'	System	11 Feb 2021 19:38:56

US3562229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:23:14
User entered '16'	(b) (4) Dhwani Shah (b) (4) (b) (4)	11 Feb 2021 19:38:56

US3562229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User entered 'breaths/min'	System	11 Feb 2021 19:38:56

US3562229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:23:14
User entered '132'	(b) (4) Dhwani Shah (b) (4) (b) (4)	11 Feb 2021 19:38:56

US3562229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User entered 'mmHg'	System	11 Feb 2021 19:38:56

US3562229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:23:14
User entered '78'	(b) (4) Dhwani Shah (b) (4) (b) (4)	11 Feb 2021 19:38:56

US3562229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 08:16:08

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User entered 'mmHg'	System	11 Feb 2021 19:38:56

US3562229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:08

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User accepted default value 'Post-Dose (POSTDOSE)'	Dhwani Shah (b) (4) (b) (4)	11 Feb 2021 19:38:56

US3562229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:23:14
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	11 Feb 2021 19:38:56

US3562229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:08

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:23:14
User entered '11 Feb 2021'	(b) (4) Dhwani Shah (b) (4) (b) (4)	11 Feb 2021 19:38:56

US3562229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:23:14
User entered '10:45'	(b) (4) Dhwani Shah (b) (4) (b) (4)	11 Feb 2021 19:38:56

US3562229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User entered '11 Feb 2021 10:45'	System	11 Feb 2021 19:38:56

US3562229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:08

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:23:14
User entered '97.3' F	(b) (4) Dhwani Shah (b) (4) (b) (4)	11 Feb 2021 19:38:56

US3562229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:23:14
User entered 'Oral (Oral)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	11 Feb 2021 19:38:56

US3562229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:23:14
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	11 Feb 2021 19:38:56

US3562229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:23:14
User entered '60'	(b) (4) Dhwani Shah (b) (4) (b) (4)	11 Feb 2021 19:38:56

US3562229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User entered 'bpm'	System	11 Feb 2021 19:38:56

US3562229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:23:14
User entered '16'	(b) (4) Dhwani Shah (b) (4) (b) (4)	11 Feb 2021 19:38:56

US3562229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User entered 'breaths/min'	System	11 Feb 2021 19:38:56

US3562229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:08

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:23:14
User entered '132'	(b) (4) Dhwani Shah (b) (4) (b) (4)	11 Feb 2021 19:38:56

US3562229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User entered 'mmHg'	System	11 Feb 2021 19:38:56

US3562229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:08

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:23:14
User entered '82'	(b) (4) Dhwani Shah (b) (4) (b) (4)	11 Feb 2021 19:38:56

US3562229

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 08:16:08

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User entered 'mmHg'	System	11 Feb 2021 19:38:56

US3562229

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:16:08

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:23:14
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	11 Feb 2021 19:39:05

US3562229

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:16:08

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:23:14
User entered '11 Feb 2021'	(b) (4) Dhwani Shah (b) (4) (b) (4)	11 Feb 2021 19:39:05

US3562229

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:16:08

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:23:14
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	11 Feb 2021 19:39:33

US3562229

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:16:08

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:23:14
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	11 Feb 2021 19:39:33

US3562229

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:16:08

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 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:23:14
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	11 Feb 2021 19:39:33

US3562229

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:16:08

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User entered 'mRNA-1273'	System	11 Feb 2021 19:39:33
DataPoint set to visible.	System	19 Jan 2021 17:09:32

US3562229

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:16:08

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:23:14
User entered '11 Feb 2021'	(b) (4) Dhwani Shah (b) (4) (b) (4)	11 Feb 2021 19:39:33

US3562229

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:23:14
User entered '10:12'	(b) (4) Dhwani Shah (b) (4) (b) (4)	11 Feb 2021 19:39:33

US3562229

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User entered '11 Feb 2021 10:12'	System	11 Feb 2021 19:39:33

US3562229

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:23:14
User entered 'Left Arm (LEFT ARM)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	11 Feb 2021 19:39:33

US3562229

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User entered 'ONCE'	System	11 Feb 2021 19:39:33

US3562229

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User entered 'INTRAMUSCULAR'	System	11 Feb 2021 19:39:33

US3562229

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:23:14
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	11 Feb 2021 19:39:40

US3562229

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User entered 'l'	System	11 Feb 2021 19:39:40

US3562229

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:08

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4) (b) (4)	11 Mar 2021 17:36:25
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	24 Feb 2021 20:58:26
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	23 Feb 2021 17:58:45
User entered 'Yes (Y)'	Sabrina Bolland (b) (4) (b) (4)	23 Feb 2021 17:58:45

US3562229

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:08

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User closed query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	05 Mar 2021 05:30:57
User entered '19 Feb 2021' reason for change: New Information	Dhwani Shah (b) (4)	03 Mar 2021 19:24:19
Query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'confirmed as it is' (Site from System).	Dhwani Shah (b) (4)	03 Mar 2021 19:24:02
User opened query 'OL Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after OL-D29 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	25 Feb 2021 22:55:47
User entered '25 Feb 2021' reason for change: New Information	Sabrina Bolland (b) (4)	25 Feb 2021 22:55:47
User entered '19 Feb 2021' reason for change: Data Entry Error	Dhwani Shah (b) (4)	24 Feb 2021 20:58:26
User entered empty.	Sabrina Bolland (b) (4)	23 Feb 2021 17:58:45

US3562229

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:08

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) Sabrina Bolland (b) (4)	23 Feb 2021 17:58:45

US3562229

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 08:16:08

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered 'contact attempted on 19Feb2021, 22Feb2021, 23Feb2021.'	(b) (4) Sabrina Bolland (b) (4)	23 Feb 2021 17:58:45

US3562229

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	11 Mar 2021 17:36:25
User entered 'Yes (Y)'	(b) (4) Sabrina Bolland (b) (4)	23 Feb 2021 17:58:56

US3562229

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 08:16:08

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User entered 'l'	System	23 Feb 2021 17:58:56

US3562229

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:16:08

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:23:14
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	11 Mar 2021 20:17:08

US3562229

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:23:14
User entered '11 Mar 2021'	(b) (4) Dhwani Shah (b) (4) (b) (4)	11 Mar 2021 20:17:08

US3562229

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:23:14
User entered 'Clinic (Clinic)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	11 Mar 2021 20:17:08

US3562229

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 08:16:08

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User entered 'OLD57'	System	11 Mar 2021 20:17:08

US3562229

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:08

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:23:14
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	11 Mar 2021 20:17:40

US3562229

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:08

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:23:14
User entered '11 Mar 2021'	(b) (4) Dhwani Shah (b) (4) (b) (4)	11 Mar 2021 20:17:40

US3562229

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:23:14
User entered '12:55'	(b) (4) Dhwani Shah (b) (4) (b) (4)	11 Mar 2021 20:17:40

US3562229

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User entered '11 Mar 2021 12:55'	System	11 Mar 2021 20:17:40

US3562229

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:23:14
User entered '98.4' F	(b) (4) Dhwani Shah (b) (4) (b) (4)	11 Mar 2021 20:17:40

US3562229

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:08

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:23:14
User entered 'Oral (Oral)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	11 Mar 2021 20:17:40

US3562229

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:08

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:23:14
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	11 Mar 2021 20:17:40

US3562229

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:08

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:23:14
User entered '80'	(b) (4) Dhwani Shah (b) (4) (b) (4)	11 Mar 2021 20:17:40

US3562229

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:08

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User entered 'bpm'	System	11 Mar 2021 20:17:40

US3562229

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:23:14
User entered '12'	(b) (4) Dhwani Shah (b) (4) (b) (4)	11 Mar 2021 20:17:40

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:08

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User entered 'breaths/min'	System	11 Mar 2021 20:17:40

US3562229

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:23:14
User entered '122'	(b) (4) Dhwani Shah (b) (4) (b) (4)	11 Mar 2021 20:17:40

US3562229

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:08

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User entered 'mmHg'	System	11 Mar 2021 20:17:40

US3562229

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:23:14
User entered '81'	(b) (4) Dhwani Shah (b) (4) (b) (4)	11 Mar 2021 20:17:40

US3562229

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:08

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User entered 'mmHg'	System	11 Mar 2021 20:17:40

US3562229

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:08

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 08:16:08

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26

US3562229

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:16:08

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:23:14
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	11 Mar 2021 20:17:59

US3562229

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 08:16:08

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:23:14
User entered '11 Mar 2021'	(b) (4) Dhwani Shah (b) (4) (b) (4)	11 Mar 2021 20:17:59

US3562229

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:16:08

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:23:14
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	11 Mar 2021 20:18:14

US3562229

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:16:08

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:23:14
User entered '11 Mar 2021'	(b) (4) Dhwani Shah (b) (4) (b) (4)	11 Mar 2021 20:18:14

US3562229

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:16:08

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:23:14
User entered '13:00'	(b) (4) Dhwani Shah (b) (4) (b) (4)	11 Mar 2021 20:18:14

US3562229

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:39:26
User entered '11 Mar 2021 13:00'	System	11 Mar 2021 20:18:14

US3562229

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 08:16:08

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:03:58
User signature succeeded.	Joseph Davis (b) (4) (b) (4)	08 Apr 2021 22:10:23
User closed query 'Per DM CLR: Per Safety Follow Up Diary Day 159 (23MAR2021) 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 12:48:38
Query 'Per DM CLR: Per Safety Follow Up Diary Day 159 (23MAR2021) 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' answered with 'saw pcp for dizziness and balance issue which is already added to AE' (Site from DM).	Dhwani Shah (b) (4) (b) (4)	05 Apr 2021 22:35:56
User opened query 'Per DM CLR: Per Safety Follow Up Diary Day 159 (23MAR2021) 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 06:30:12
User entered 'Yes (Y)' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	09 Nov 2020 17:18:50
User entered 'No (N)'	Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:48:16

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:08

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:18

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:08

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:18
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User coded data point as SOC: Gastrointestinal disorders, HLGIT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\23.0.	Coder Import (b) (4)	12 Nov 2020 15:55:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	12 Nov 2020 15:55:31
Data point term sent to Coder	System	12 Nov 2020 15:54:34
User closed query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. ' (Site from System).	System	12 Nov 2020 15:54:01
Query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. ' answered with 'updated' (Site from System).	Dhwani Shah (b) (4)	12 Nov 2020 15:54:01
User entered 'NAUSEA' reason for change: Data Entry Error	Dhwani Shah (b) (4)	12 Nov 2020 15:53:54
User opened query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. ' (Site from System).	Coder Import (b) (4)	11 Nov 2020 23:00:38
Data point term sent to Coder	System	09 Nov 2020 17:20:18
User entered 'nausea and Fatigue'	Dhwani Shah (b) (4)	09 Nov 2020 17:19:39

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:08

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:18
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Nov 2020 17:19:39

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:08

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:18
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Nov 2020 17:19:39

US3562229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:08

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:18
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Nov 2020 17:19:39

US3562229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:18
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered '29 Oct 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Nov 2020 17:19:39

US3562229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:08

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:18
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Nov 2020 17:19:39

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:08

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:18
User entered empty.	System	09 Nov 2020 17:19:39

US3562229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:18
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Nov 2020 17:19:39

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:08

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:18
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered '30 Oct 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Nov 2020 17:19:39

US3562229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:08

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:18
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Nov 2020 17:19:39

US3562229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:08

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:18
User entered empty.	System	09 Nov 2020 17:19:39

US3562229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:08

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:18
User signature succeeded.	Joseph Davis (b) (4) (b) (4)	09 Apr 2021 18:45:30
User entered 'Grade 1/Mild (Grade 1/Mild)'	Dhwani Shah (b) (4) (b) (4)	09 Nov 2020 17:19:39

US3562229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:08

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:18
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Nov 2020 17:19:39

US3562229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:08

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:18
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Nov 2020 17:19:39

US3562229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:08

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:18
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Nov 2020 17:19:39

US3562229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:18
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Nov 2020 17:19:39

US3562229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:08

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:18
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Nov 2020 17:19:39

US3562229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:08

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:18
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Nov 2020 17:19:39

US3562229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:08

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:18
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Nov 2020 17:19:39

US3562229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:08

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:18
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Nov 2020 17:19:39

US3562229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:18
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Nov 2020 17:19:39

US3562229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:18
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Nov 2020 17:19:39

US3562229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:08

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:18
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Nov 2020 17:19:39

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:08

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:18
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered 'Not Related (NOT RELATED)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Nov 2020 17:19:39

US3562229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:08

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:18
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered 'Not Related (NOT RELATED)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Nov 2020 17:19:39

US3562229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:08

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:18
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered 'None (NONE)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Nov 2020 17:19:39

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:08

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:18
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered 'l'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Nov 2020 17:19:39

US3562229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:08

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:18
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Nov 2020 17:19:39

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:08

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:18
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Nov 2020 17:19:39

US3562229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:08

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:18
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Dhwani Shah (b) (4)	09 Nov 2020 17:19:39

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:08

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:18
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Nov 2020 17:19:39

US3562229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:08

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:18
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Nov 2020 17:19:39

US3562229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:08

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:18
User entered '0'	System	09 Nov 2020 17:19:39

US3562229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:08

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:18
User entered '0'	System	09 Nov 2020 17:19:39

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 08:16:08

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:18

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:16:08

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:16:08

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\23.0.	Coder Import (b) (4)	12 Nov 2020 15:56:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	12 Nov 2020 15:56:31
Data point term sent to Coder	System	12 Nov 2020 15:55:35
User entered 'Fatigue'	Dhwani Shah (b) (4)	12 Nov 2020 15:54:38

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:16:08

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Nov 2020 15:54:38

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:16:08

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Nov 2020 15:54:38

US3562229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:16:08

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Nov 2020 15:54:38

US3562229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:16:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered '29 Oct 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Nov 2020 15:54:38

US3562229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:16:08

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Nov 2020 15:54:38

US3562229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:16:08

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User entered empty.	System	12 Nov 2020 15:54:38

US3562229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:16:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Nov 2020 15:54:38

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:16:08

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered '30 Oct 2020'	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Nov 2020 15:54:38

US3562229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:16:08

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Nov 2020 15:54:38

US3562229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:16:08

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User entered empty.	System	12 Nov 2020 15:54:38

US3562229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:16:08

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Nov 2020 15:54:38

US3562229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:16:08

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Nov 2020 15:54:38

US3562229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:16:08

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Nov 2020 15:54:38

US3562229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:16:08

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Nov 2020 15:54:38

US3562229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:16:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Nov 2020 15:54:38

US3562229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:16:08

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Nov 2020 15:54:38

US3562229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:16:08

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Nov 2020 15:54:38

US3562229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:16:08

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Nov 2020 15:54:38

US3562229

Folder: Adverse Events

Form: Adverse Events (2)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Nov 2020 15:54:38

US3562229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:16:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Nov 2020 15:54:38

US3562229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:16:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Nov 2020 15:54:38

US3562229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:16:08

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Nov 2020 15:54:38

US3562229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:16:08

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered 'Not Related (NOT RELATED)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Nov 2020 15:54:38

US3562229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:16:08

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered 'Not Related (NOT RELATED)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Nov 2020 15:54:38

US3562229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:16:08

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered 'None (NONE)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Nov 2020 15:54:38

US3562229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:16:08

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered 'l'	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Nov 2020 15:54:38

US3562229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:16:08

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Nov 2020 15:54:38

US3562229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:16:08

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Nov 2020 15:54:38

US3562229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:16:08

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Joseph Davis (b) (4) (b) (4)	09 Apr 2021 18:45:30
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Dhwani Shah (b) (4) (b) (4)	12 Nov 2020 15:54:38

US3562229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:16:08

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Nov 2020 15:54:38

US3562229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:16:08

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	12 Nov 2020 15:54:38

US3562229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:16:08

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User entered '0'	System	12 Nov 2020 15:54:38

US3562229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:16:08

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User entered '0'	System	12 Nov 2020 15:54:38

US3562229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 08:16:08

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25

US3562229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:08

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:25:52

US3562229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:08

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:25:52
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Neurological signs and symptoms NEC, PT: Dizziness, LLT: Dizziness - version MedDRA\\23.0.	Coder Import (b) (4)	29 Mar 2021 07:03:09
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	29 Mar 2021 07:03:09
Data point term sent to Coder	System	26 Mar 2021 19:32:08
User entered 'dizeness'	Dhwani Shah (b) (4)	26 Mar 2021 19:31:08

US3562229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:08

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:25:52
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:31:08

US3562229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:08

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:25:52
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:31:08

US3562229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:08

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:25:52
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:31:08

US3562229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:25:52
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered '01 Feb 2021'	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:31:08

US3562229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:08

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:25:52
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:31:08

US3562229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:08

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:25:52
User entered empty.	System	26 Mar 2021 19:31:08

US3562229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:25:52
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
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)	07 Apr 2021 12:51:58
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 'updated' (Site from DM).	Dhwani Shah (b) (4)	05 Apr 2021 22:19:39
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	05 Apr 2021 22:19:21
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)	05 Apr 2021 10:33:21
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	26 Mar 2021 19:31:08

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:08

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:25:52
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4), (b) (6)	07 Apr 2021 12:52:00
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered with 'updated' (Site from System).	Dhwani Shah (b) (4)	05 Apr 2021 22:32:57
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	05 Apr 2021 22:19:21
User entered '01 Mar 2021' reason for change: Data Entry Error	Dhwani Shah (b) (4)	05 Apr 2021 22:19:21
User entered empty.	Dhwani Shah (b) (4)	26 Mar 2021 19:31:08

US3562229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:08

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:25:52
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:31:08

US3562229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:08

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:25:52
User entered empty.	System	26 Mar 2021 19:31:08

US3562229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:08

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:25:52
User signature succeeded.	Joseph Davis (b) (4) (b) (4)	09 Apr 2021 18:45:30
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:31:08

US3562229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:08

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:25:52
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:31:08

US3562229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:08

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:25:52
User signature succeeded.	Joseph Davis (b) (4) (b) (4)	09 Apr 2021 18:45:30
User entered '0'	Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:31:08

US3562229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:08

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:25:52
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:31:08

US3562229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:25:52
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:31:08

US3562229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:08

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:25:52
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:31:08

US3562229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:08

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:25:52
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:31:08

US3562229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:08

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:25:52
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:31:08

US3562229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:08

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:25:52
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:31:08

US3562229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:25:52
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:31:08

US3562229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:25:52
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:31:08

US3562229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:08

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:25:52
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:31:08

US3562229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:08

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:25:52
User signature succeeded.	Joseph Davis (b) (4) (b) (4)	09 Apr 2021 18:45:30
User entered 'Not Related (NOT RELATED)'	Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:31:08

US3562229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:08

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:25:52
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered 'Not Related (NOT RELATED)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:31:08

US3562229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:08

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:25:52
User signature succeeded.	Joseph Davis (b) (4) (b) (4)	09 Apr 2021 18:45:30
User entered 'Not Applicable (NOT APPLICABLE)'	Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:31:08

US3562229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:08

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:25:52
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered 'l'	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:31:08

US3562229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:08

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:25:52
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:31:08

US3562229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:08

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:25:52
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:31:08

US3562229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:08

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:25:52
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4) Dhwani Shah (b) (4)	05 Apr 2021 22:33:42
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Dhwani Shah (b) (4)	26 Mar 2021 19:31:08

US3562229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:08

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:25:52
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:31:08

US3562229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:08

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:25:52
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:31:08

US3562229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:08

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:25:52
User entered '0'	System	26 Mar 2021 19:31:08

US3562229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:08

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:25:52
User entered '1'	System	26 Mar 2021 19:31:08

US3562229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 08:16:08

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:25:52

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:16:08

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLT: Muscle disorders, HLT: Muscle related signs and symptoms NEC, PT: Muscle spasms, LLT: Muscle cramp - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Apr 2021 10:50:54
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Apr 2021 10:50:54
User signature succeeded.	Joseph Davis (b) (4) (b) (4)	09 Apr 2021 18:45:30
Data point term sent to Coder	System	09 Apr 2021 16:13:59
User entered 'MUSCLE CRAMPING (BOTH SIDE OF BODY)' reason for change: Data Entry Error	Dhwani Shah (b) (4) (b) (4)	09 Apr 2021 16:13:21
Data point term sent to Coder	System	09 Apr 2021 16:12:58
User closed query 'CDM Coding, please split the term 'MUSCLE CRAMPING AND TINGLING (BOTH SIDE OF BODY)' into separate records, as 'MUSCLE CRAMPING' and 'TINGLING (BOTH SIDE OF BODY) reporting each term separately with all relevant information e.g. start and stop dates etc. ' (Site from System).	System	09 Apr 2021 16:12:54
Query 'CDM Coding, please split the term 'MUSCLE CRAMPING AND TINGLING (BOTH SIDE OF BODY)' into separate records, as 'MUSCLE CRAMPING' and 'TINGLING (BOTH SIDE OF BODY) reporting each term separately with all relevant information e.g. start and stop dates etc. ' answered with 'Updated' (Site from System).	Dhwani Shah (b) (4) (b) (4)	09 Apr 2021 16:12:54
User opened query 'CDM Coding, please split the term 'MUSCLE CRAMPING AND TINGLING (BOTH SIDE OF BODY)' into separate records, as 'MUSCLE CRAMPING' and 'TINGLING (BOTH SIDE OF BODY) reporting each term separately with all relevant information e.g. start and stop dates etc. ' (Site from System).	Coder Import (b) (4) (b) (4)	08 Apr 2021 05:48:32
Data point term sent to Coder	System	26 Mar 2021 19:33:11
User entered 'muscle cramping and tingling (Both side of body)'	Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:32:25

US3562229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:16:08

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:32:25

US3562229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:16:08

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:32:25

US3562229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:16:08

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:32:25

US3562229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:16:08

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered '01 Mar 2021'	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:32:25

US3562229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:16:08

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:32:25

US3562229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:16:08

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Mar 2021 19:32:25

US3562229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:16:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
	(b) (4)	
User entered 'Yes (Y)'	Dhwani Shah (b) (4)	26 Mar 2021 19:32:25
	(b) (4)	

US3562229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:16:08

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:32:25

US3562229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:16:08

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:32:25

US3562229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:16:08

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Mar 2021 19:32:25

US3562229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:16:08

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Dhwani Shah (b) (4)	26 Mar 2021 19:32:25

US3562229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:16:08

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:32:25

US3562229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:16:08

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:32:25

US3562229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:16:08

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:32:25

US3562229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:16:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:32:25

US3562229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:16:08

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:32:25

US3562229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:16:08

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:32:25

US3562229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:16:08

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:32:25

US3562229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:16:08

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:32:25

US3562229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:16:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:32:25

US3562229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:16:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:32:25

US3562229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:16:08

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:32:25

US3562229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:16:08

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered 'Not Related (NOT RELATED)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:32:25

US3562229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:16:08

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered 'Not Related (NOT RELATED)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:32:25

US3562229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:16:08

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:32:25

US3562229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:16:08

None

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered 'l'	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:32:25

US3562229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:16:08

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:32:25

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:16:08

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
	(b) (4)	
User entered '0'	Dhwani Shah (b) (4)	26 Mar 2021 19:32:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:16:08

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:32:25

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:16:08

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:32:25

US3562229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:16:08

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:32:25

US3562229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:16:08

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	26 Mar 2021 19:32:25

US3562229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 08:16:08

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	26 Mar 2021 19:32:25

US3562229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:16:08

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:08

US3562229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:16:08

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:08
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Fall, LLT: Fall - version MedDRA\23.0.	Coder Import (b) (4)	29 Mar 2021 20:32:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	29 Mar 2021 20:32:16
Data point term sent to Coder	System	29 Mar 2021 20:31:32
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Fall, LLT: Fall - version MedDRA\23.0.	Coder Import (b) (4)	29 Mar 2021 20:31:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	29 Mar 2021 20:31:16
User closed query 'DM-Coding: for AE term FALL (BALANCE ISSUE), Please provide a unifying diagnosis for this reported event or split to report each event into a separate record, example: 1) FALL 2) BALANCE ISSUE or Balance disorder, Disequilibrium syndrome etc. ' (Site from System).	System	29 Mar 2021 20:30:44
Query 'DM-Coding: for AE term FALL (BALANCE ISSUE), Please provide a unifying diagnosis for this reported event or split to report each event into a separate record, example: 1) FALL 2) BALANCE ISSUE or Balance disorder, Disequilibrium syndrome etc. ' answered with 'updated' (Site from System).	Dhwani Shah (b) (4)	29 Mar 2021 20:30:44
Data point term sent to Coder	System	29 Mar 2021 20:30:31
User entered 'FALL' reason for change: Data Entry Error	Dhwani Shah (b) (4)	29 Mar 2021 20:30:27
User opened query 'DM-Coding: for AE term FALL (BALANCE ISSUE), Please provide a unifying diagnosis for this reported event or split to report each event into a separate record, example: 1) FALL 2) BALANCE ISSUE or Balance disorder, Disequilibrium syndrome etc. ' (Site from System).	Coder Import (b) (4)	29 Mar 2021 07:19:56

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:16:08

[Adverse event](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	26 Mar 2021 19:34:12
User entered 'Fall (Balance issue)'	Dhwani Shah (b) (4)	26 Mar 2021 19:33:46
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:16:08

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:08
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:33:46

US3562229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:16:08

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:08
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:33:46

US3562229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:16:08

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:08
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:33:46

US3562229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:16:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:08
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered '01 Mar 2021'	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:33:46

US3562229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:16:08

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:08
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:33:46

US3562229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:16:08

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:08
User entered empty.	System	26 Mar 2021 19:33:46

US3562229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:16:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:08
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:33:46

US3562229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:16:08

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:08
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4)	26 Mar 2021 19:33:53
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	26 Mar 2021 19:33:53
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	26 Mar 2021 19:33:46
User entered '01 Mar 2021'	Dhwani Shah (b) (4)	26 Mar 2021 19:33:46
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:16:08

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:08
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:33:46

US3562229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:16:08

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:08
User entered empty.	System	26 Mar 2021 19:33:46

US3562229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:16:08

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:08
User signature succeeded.	Joseph Davis (b) (4) (b) (4)	09 Apr 2021 18:45:30
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:33:46

US3562229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:16:08

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:08
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:33:46

US3562229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:16:08

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:08
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:33:46

US3562229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:16:08

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:08
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:33:46

US3562229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:16:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:08
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:33:46

US3562229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:16:08

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:08
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:33:46

US3562229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:16:08

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:08
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:33:46

US3562229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:16:08

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:08
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:33:46

US3562229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:16:08

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:08
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:33:46

US3562229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:16:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:08
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:33:46

US3562229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:16:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:08
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:33:46

US3562229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:16:08

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:08
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:33:46

US3562229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:16:08

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:08
User signature succeeded.	Joseph Davis (b) (4) (b) (4)	09 Apr 2021 18:45:30
User entered 'Not Related (NOT RELATED)'	Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:33:46

US3562229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:16:08

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:08
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered 'Not Related (NOT RELATED)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:33:46

US3562229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:16:08

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:08
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Dhwani Shah (b) (4)	26 Mar 2021 19:33:46

US3562229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:16:08

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:08
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered 'l'	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:33:46

US3562229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:16:08

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:08
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:33:46

US3562229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:16:08

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:08
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:33:46

US3562229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:16:08

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:08
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4) Dhwani Shah (b) (4)	26 Mar 2021 19:33:53
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Dhwani Shah (b) (4)	26 Mar 2021 19:33:46

US3562229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:16:08

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:08
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:33:46

US3562229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:16:08

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:08
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	26 Mar 2021 19:33:46

US3562229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:16:08

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:08
User entered '0'	System	26 Mar 2021 19:33:46

US3562229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:16:08

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:08
User entered '1'	System	26 Mar 2021 19:33:46

US3562229

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 08:16:08

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:08

US3562229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:16:08

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:01

US3562229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:16:08

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:01
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User closed query 'Per DM CLR: Please update AE term to reflect a specific medical condition/diagnosis as appropriate. Please reconcile with the Con Med eCRF as necessary. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 12:48:07
Query 'Per DM CLR: Please update AE term to reflect a specific medical condition/diagnosis as appropriate. Please reconcile with the Con Med eCRF as necessary. ' answered with 'no specific medical condition per pt ' (Site from DM).	Dhwani Shah (b) (4)	05 Apr 2021 22:17:44
User opened query 'Per DM CLR: Please update AE term to reflect a specific medical condition/diagnosis as appropriate. Please reconcile with the Con Med eCRF as necessary. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 10:33:37
User coded data point as SOC: Nervous system disorders, HLG: Neurological disorders NEC, HLT: Coordination and balance disturbances, PT: Balance disorder, LLT: Balance disorder - version MedDRA\23.0.	Coder Import (b) (4)	29 Mar 2021 20:33:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	29 Mar 2021 20:33:24
Data point term sent to Coder System	System	29 Mar 2021 20:32:34
User entered 'Balance issue'	Dhwani Shah (b) (4)	29 Mar 2021 20:31:38

US3562229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:16:08

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:01
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 20:31:38

US3562229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:16:08

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:01
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 20:31:38

US3562229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:16:08

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:01
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 20:31:38

US3562229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:16:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:01
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered '01 Mar 2021'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 20:31:38

US3562229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:16:08

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:01
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 20:31:38

US3562229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:16:08

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:01
User entered empty.	System	29 Mar 2021 20:31:38

US3562229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:16:08

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:01
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 20:31:38

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:16:08

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:01
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered '01 Mar 2021'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 20:31:38

US3562229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:16:08

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:01
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 20:31:38

US3562229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:16:08

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:01
User entered empty.	System	29 Mar 2021 20:31:38

US3562229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:16:08

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:01
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 20:31:38

US3562229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:16:08

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:01
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 20:31:38

US3562229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:16:08

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:01
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 20:31:38

US3562229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:16:08

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:01
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 20:31:38

US3562229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:16:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:01
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 20:31:38

US3562229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:16:08

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:01
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 20:31:38

US3562229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:16:08

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:01
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 20:31:38

US3562229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:16:08

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:01
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 20:31:38

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:16:08

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:01
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 20:31:38

US3562229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:16:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:01
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 20:31:38

US3562229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:16:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:01
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 20:31:38

US3562229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:16:08

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:01
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 20:31:38

US3562229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:16:08

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:01
User signature succeeded.	Joseph Davis (b) (4) (b) (4)	09 Apr 2021 18:45:30
User entered 'Not Related (NOT RELATED)'	Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 20:31:38

US3562229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:16:08

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:01
User signature succeeded.	Joseph Davis (b) (4) (b) (4)	09 Apr 2021 18:45:30
User entered 'Not Related (NOT RELATED)'	Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 20:31:38

US3562229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:16:08

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:01
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 20:31:38

US3562229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:16:08

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:01
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered 'l'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 20:31:38

US3562229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:16:08

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:01
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 20:31:38

US3562229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:16:08

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:01
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 20:31:38

US3562229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:16:08

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:01
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Dhwani Shah (b) (4)	29 Mar 2021 20:31:38

US3562229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:16:08

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:01
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 20:31:38

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:16:08

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:01
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	29 Mar 2021 20:31:38

US3562229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:16:08

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:01
User entered '0'	System	29 Mar 2021 20:31:38

US3562229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:16:08

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:01
User entered '0'	System	29 Mar 2021 20:31:38

US3562229

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 08:16:08

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:01

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:16:08

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLG: Neurological disorders NEC, HLT: Paraesthesias and dysaesthesias, PT: Paraesthesia, LLT: Tingling - version MedDRA\23.0.	Coder Import (b) (4)	14 Apr 2021 08:48:58
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	14 Apr 2021 08:48:58
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
Data point term sent to Coder System	(b) (4)	09 Apr 2021 16:15:04
User entered 'Tingling Both side of the Body'	Dhwani Shah (b) (4)	09 Apr 2021 16:14:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:16:08

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Apr 2021 16:14:11

US3562229

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:16:08

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Apr 2021 16:14:11

US3562229

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:16:08

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Apr 2021 16:14:11

US3562229

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:16:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered '01 Mar 2021'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Apr 2021 16:14:11

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:16:08

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
	(b) (4)	
User entered empty.	Dhwani Shah (b) (4)	09 Apr 2021 16:14:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:16:08

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 16:14:11

US3562229

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:16:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Apr 2021 16:14:11

US3562229

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:16:08

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Apr 2021 16:14:11

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:16:08

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Apr 2021 16:14:11

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:16:08

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 16:14:11

US3562229

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:16:08

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Apr 2021 16:14:11

US3562229

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:16:08

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Apr 2021 16:14:11

US3562229

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:16:08

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Apr 2021 16:14:11

US3562229

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:16:08

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Apr 2021 16:14:11

US3562229

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:16:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Apr 2021 16:14:11

US3562229

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:16:08

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
	(b) (4)	
User entered empty.	Dhwani Shah (b) (4)	09 Apr 2021 16:14:11
	(b) (4)	

US3562229

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:16:08

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Apr 2021 16:14:11

US3562229

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:16:08

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Apr 2021 16:14:11

US3562229

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:16:08

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Apr 2021 16:14:11

US3562229

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:16:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
	(b) (4)	
User entered '0'	Dhwani Shah (b) (4)	09 Apr 2021 16:14:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:16:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Apr 2021 16:14:11

US3562229

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:16:08

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Apr 2021 16:14:11

US3562229

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:16:08

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered 'Not Related (NOT RELATED)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Apr 2021 16:14:11

US3562229

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:16:08

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered 'Not Related (NOT RELATED)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Apr 2021 16:14:11

US3562229

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:16:08

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Apr 2021 16:14:11

US3562229

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:16:08

None

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered 'l'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Apr 2021 16:14:11

US3562229

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:16:08

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Apr 2021 16:14:11

US3562229

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:16:08

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Apr 2021 16:14:11

US3562229

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:16:08

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) Dhwani Shah (b) (4)	09 Apr 2021 16:14:11

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:16:08

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
	(b) (4)	
User entered empty.	Dhwani Shah (b) (4)	09 Apr 2021 16:14:11
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:16:08

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	09 Apr 2021 18:45:30
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	09 Apr 2021 16:14:11

US3562229

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:16:08

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	09 Apr 2021 16:14:11

US3562229

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 08:16:08

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	09 Apr 2021 16:14:11

US3562229

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:16:08

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 15:04:47
User entered 'USA-US071-2021-mRNA-1273-P301000007'	System	22 Apr 2021 15:03:04
User entered 'New'	(b) (4), (b) (6)	22 Apr 2021 15:03:04

US3562229

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:16:08

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Paraesthesias and dysaesthesias, PT: Paraesthesia, LLT: Paresthesia - version MedDRA\23.0.	Coder Import (b) (4)	24 Apr 2021 10:53:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	24 Apr 2021 10:53:42
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
Data point term sent to Coder	System	22 Apr 2021 15:15:42
User closed query 'CDM-Coding: Please either provide a single clinical diagnosis for this reported event "MILD WEEKNESS OF RIGHT SIDE, PARESTHESIA" or split to report each event separately to capture coding for all terms. Example: 1) MILD WEEKNESS OF RIGHT SIDE 2) PARESTHESIA. Thank you. ' (Site from System).	System	22 Apr 2021 15:15:41
Query 'CDM-Coding: Please either provide a single clinical diagnosis for this reported event "MILD WEEKNESS OF RIGHT SIDE, PARESTHESIA" or split to report each event separately to capture coding for all terms. Example: 1) MILD WEEKNESS OF RIGHT SIDE 2) PARESTHESIA. Thank you. ' answered with 'per medical records it is one final diagnosis for hospitalization ! Can not split word or can not change term confirmed as it is ' (Site from System).	Dhwani Shah (b) (4)	22 Apr 2021 15:15:41
User entered 'MILD WEEKNESS OF RIGHT SIDE PARESTHESIA' reason for change: Data Entry Error	Dhwani Shah (b) (4)	22 Apr 2021 15:14:56
User opened query 'CDM-Coding: Please either provide a single clinical diagnosis for this reported event "MILD WEEKNESS OF RIGHT SIDE, PARESTHESIA" or split to report each event separately to capture coding for all terms. Example: 1) MILD WEEKNESS OF RIGHT SIDE 2) PARESTHESIA. Thank you. ' (Site from System).	Coder Import (b) (4)	22 Apr 2021 10:02:45
Data point term sent to Coder	System	21 Apr 2021 22:08:36
User entered 'Mild weekness of right side, Paresthesia'	Dhwani Shah (b) (4)	21 Apr 2021 22:07:42

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:16:08

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	21 Apr 2021 22:07:42

US3562229

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:16:08

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	21 Apr 2021 22:07:42

US3562229

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:16:08

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	21 Apr 2021 22:07:42

US3562229

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:16:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
User entered '16 Apr 2021'	(b) (4) Dhwani Shah (b) (4) (b) (4)	21 Apr 2021 22:07:42

US3562229

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:16:08

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	21 Apr 2021 22:07:42

US3562229

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:16:08

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Apr 2021 22:07:42

US3562229

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:16:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	21 Apr 2021 22:07:42

US3562229

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:16:08

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
User entered '18 Apr 2021'	(b) (4) Dhwani Shah (b) (4) (b) (4)	21 Apr 2021 22:07:42

US3562229

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:16:08

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	21 Apr 2021 22:07:42

US3562229

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:16:08

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Apr 2021 22:07:42

US3562229

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:16:08

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
User entered 'Grade 4 (Grade 4)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	21 Apr 2021 22:07:42

US3562229

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:16:08

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	21 Apr 2021 22:07:42

US3562229

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:16:08

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	21 Apr 2021 22:07:42

US3562229

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:16:08

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	21 Apr 2021 22:07:42

US3562229

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:16:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
User entered 'l'	(b) (4) Dhwani Shah (b) (4) (b) (4)	21 Apr 2021 22:07:42

US3562229

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:16:08

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
User entered '16 Apr 2021'	(b) (4) Dhwani Shah (b) (4) (b) (4)	21 Apr 2021 22:07:42

US3562229

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:16:08

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
User entered '18 Apr 2021'	(b) (4) Dhwani Shah (b) (4) (b) (4)	21 Apr 2021 22:07:42

US3562229

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:16:08

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	21 Apr 2021 22:07:42

US3562229

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:16:08

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	21 Apr 2021 22:07:42

US3562229

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:16:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	21 Apr 2021 22:07:42

US3562229

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:16:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	21 Apr 2021 22:07:42

US3562229

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:16:08

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	21 Apr 2021 22:07:42

US3562229

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:16:08

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
User entered 'Not Related (NOT RELATED)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	21 Apr 2021 22:07:42

US3562229

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:16:08

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
User entered 'Not Related (NOT RELATED)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	21 Apr 2021 22:07:42

US3562229

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:16:08

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	21 Apr 2021 22:07:42

US3562229

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:16:08

None

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	21 Apr 2021 22:07:42

US3562229

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:16:08

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	21 Apr 2021 22:07:42

US3562229

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:16:08

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
User entered 'l'	(b) (4) Dhwani Shah (b) (4) (b) (4)	21 Apr 2021 22:07:42

US3562229

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:16:08

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	21 Apr 2021 22:07:42

US3562229

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:16:08

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	21 Apr 2021 22:07:42

US3562229

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:16:08

[Narrative](#)

Audit	User	Time (GMT)
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 'it is already mentioned in narrative that medical records does not indicate if COVID 19 was completed ! Patient does not know about it ' (Site from Safety).	Dhwani Shah (b) (4) (b) (4)	03 May 2021 18:45:27
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)	03 May 2021 17:14:55
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)	03 May 2021 17:14:44
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)	03 May 2021 17:14:31
User signature succeeded.	Joseph Davis (b) (4) (b) (4)	23 Apr 2021 20:18:00
User entered 'this is 56 yr old patient who was admitted and neurology was consulted. the patient initially have slurred speech and right sided weakness. she also have issue with balance. per medical records did not see if covid 19 test was done at hospital or ED. updated all procedure related to SAE'	Dhwani Shah (b) (4) (b) (4)	21 Apr 2021 22:07:42

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:16:08

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 22:07:42

US3562229

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:16:08

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 22:07:42

US3562229

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 10 Jun 2021 08:16:08

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	21 Apr 2021 22:07:42

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 08:16:08

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:03:58
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:48:44

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:16:08

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	19 Oct 2020 16:51:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	19 Oct 2020 16:51:30
Data point term sent to Coder	System	19 Oct 2020 16:51:00
User entered 'LEVOTHYROXINE'	Dhwani Shah (b) (4)	19 Oct 2020 16:50:02

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:16:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:50:02

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:16:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered 'HYPOTHYROIDISM'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:50:02

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:16:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered '125'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:50:02

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:16:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
	(b) (4)	
User entered 'ug (ug)' reason for change: Data Entry Error	Dhwani Shah (b) (4)	19 Nov 2020 22:43:33
	(b) (4)	
User entered 'Other (OTHER)'	Dhwani Shah (b) (4)	19 Oct 2020 16:50:02
	(b) (4)	

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:16:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User closed query 'Per CDM: The dose unit other specify is mentioned as "MCG" which is one of the listed choices of the dose unit "ug". Kindly select the appropriate drop down and make other specify as blank.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 05:04:45
Query 'Per CDM: The dose unit other specify is mentioned as "MCG" which is one of the listed choices of the dose unit "ug". Kindly select the appropriate drop down and make other specify as blank.' answered with 'updated' (Site from DM).	Dhwani Shah (b) (4)	19 Nov 2020 22:44:21
User entered empty; reason for change Data Entry Error	(b) (4)	19 Nov 2020 22:43:33
User opened query 'Per CDM: The dose unit other specify is mentioned as "MCG" which is one of the listed choices of the dose unit "ug". Kindly select the appropriate drop down and make other specify as blank.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 11:41:00
User entered 'MCG'	Dhwani Shah (b) (4)	19 Oct 2020 16:50:02

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:16:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered 'once daily (QD)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:50:02

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:16:08

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:50:02

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:16:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered 'Oral (ORAL)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:50:02

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:16:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:50:02

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:16:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered 'UN UNK 2007'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:50:02

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:16:08

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:50:02

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:16:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:50:02

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:50:02

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:16:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:50:02

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:16:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 16:50:02

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:16:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 16:50:02

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 08:16:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Oct 2020 16:50:02

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:16:08

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: FORMOTEROL FUMARATE;MOMETASONE FUROATE, PRODUCTSYNONYM: DULERA - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	19 Oct 2020 16:54:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	19 Oct 2020 16:54:28
Data point term sent to Coder User entered 'DULERA'	System Dhwani Shah (b) (4)	19 Oct 2020 16:53:03 19 Oct 2020 16:52:14

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:16:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:52:14

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:16:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered 'Mild ASTHMA'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:52:14

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:16:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User closed query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125).' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 10:33:57
Query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125).' answered with 'updated' (Site from DM).	Dhwani Shah (b) (4)	04 Dec 2020 18:39:21
User entered '200/5' reason for change: Data Entry Error	(b) (4)	
User opened query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125).' (Site from DM).	Dhwani Shah (b) (4)	04 Dec 2020 18:39:14
User entered '200'	(b) (4), (b) (6)	24 Nov 2020 15:31:34
	Dhwani Shah (b) (4)	19 Oct 2020 16:52:14
	(b) (4)	

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:16:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
	(b) (4)	
User entered 'ug (ug)' reason for change: Data Entry Error	Dhwani Shah (b) (4)	19 Nov 2020 22:45:17
	(b) (4)	
User entered 'Other (OTHER)'	Dhwani Shah (b) (4)	19 Oct 2020 16:52:14
	(b) (4)	

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:16:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User closed query 'Per CDM: The dose unit other specify is mentioned as "MCG" which is one of the listed choices of the dose unit "ug". Kindly select the appropriate drop down and make other specify as blank.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 05:04:59
Query 'Per CDM: The dose unit other specify is mentioned as "MCG" which is one of the listed choices of the dose unit "ug". Kindly select the appropriate drop down and make other specify as blank.' answered with 'updated' (Site from DM).	Dhwani Shah (b) (4)	19 Nov 2020 22:45:29
User entered empty; reason for change Data Entry Error	(b) (4)	19 Nov 2020 22:45:17
User opened query 'Per CDM: The dose unit other specify is mentioned as "MCG" which is one of the listed choices of the dose unit "ug". Kindly select the appropriate drop down and make other specify as blank.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 11:41:36
User entered 'mcg'	Dhwani Shah (b) (4)	19 Oct 2020 16:52:14

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:16:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered 'twice daily (BID)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:52:14

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:16:08

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:52:14

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:16:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:52:14

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:16:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:52:14

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:16:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered 'un UNK 2016'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:52:14

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:16:08

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:52:14

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:16:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:52:14

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:52:14

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:16:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:52:14

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:16:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	19 Oct 2020 16:52:14

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:16:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 16:52:14

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 08:16:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Oct 2020 16:52:14

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:16:08

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
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 SULFATE, PRODUCTSYNONYM: ALBUTEROL SULFATE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	19 Oct 2020 17:18:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	19 Oct 2020 17:18:54
Data point term sent to Coder User entered 'albuterol sulfate'	System Dhwani Shah (b) (4)	19 Oct 2020 16:54:06 19 Oct 2020 16:53:15

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:16:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:53:15

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:16:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered 'mild asthma'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:53:15

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:16:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered '180'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:53:15

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:16:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
	(b) (4)	
User entered 'ug (ug)' reason for change: Data Entry Error	Dhwani Shah (b) (4)	19 Nov 2020 22:45:43
	(b) (4)	
User entered 'Other (OTHER)'	Dhwani Shah (b) (4)	19 Oct 2020 16:53:15
	(b) (4)	

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:16:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User closed query 'Per CDM: The dose unit other specify is mentioned as "MCG" which is one of the listed choices of the dose unit "ug". Kindly select the appropriate drop down and make other specify as blank.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 05:03:47
Query 'Per CDM: The dose unit other specify is mentioned as "MCG" which is one of the listed choices of the dose unit "ug". Kindly select the appropriate drop down and make other specify as blank.' answered with 'updated' (Site from DM).	Dhwani Shah (b) (4)	19 Nov 2020 22:45:50
User entered empty; reason for change Data Entry Error	(b) (4)	19 Nov 2020 22:45:43
User opened query 'Per CDM: The dose unit other specify is mentioned as "MCG" which is one of the listed choices of the dose unit "ug". Kindly select the appropriate drop down and make other specify as blank.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 11:42:55
User entered 'mcg'	Dhwani Shah (b) (4)	19 Oct 2020 16:53:15

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:16:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered 'as needed (PRN)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:53:15

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:16:08

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:53:15

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:16:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:53:15

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:16:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:53:15

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:16:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered 'un UNK 2016'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:53:15

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:16:08

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:53:15

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:16:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:53:15

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:16:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:53:15

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:16:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:53:15

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:16:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 16:53:15

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:16:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 16:53:15

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 08:16:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 16:53:15

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:16:08

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE, PRODUCTSYNONYM: PRILOSEC [OMEPRAZOLE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	19 Oct 2020 17:18:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	19 Oct 2020 17:18:53
Data point term sent to Coder User entered 'Prilosec'	System Dhwani Shah (b) (4)	19 Oct 2020 16:54:06 19 Oct 2020 16:53:50

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:16:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:53:50

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:16:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered 'gastroesophageal reflux disease'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:53:50

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:16:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered '40'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:53:50

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:16:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered 'mg (mg)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:53:50

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:16:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:53:50

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:16:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered 'once daily (QD)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:53:50

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:16:08

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:53:50

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:16:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered 'Oral (ORAL)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:53:50

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:16:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:53:50

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:16:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered 'un UNK 2003'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:53:50

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:16:08

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:53:50

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:16:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:53:50

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:16:08

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:53:50

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:16:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:53:50

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:16:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 16:53:50

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:16:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 16:53:50

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 08:16:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Oct 2020 16:53:50

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:16:08

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ESTROGENS, ATC: NATURAL AND SEMISYNTHETIC ESTROGENS, PLAIN, PRODUCT: ESTRADIOL - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	20 Oct 2020 04:38:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	20 Oct 2020 04:38:34
Data point term sent to Coder	System	19 Oct 2020 16:55:07
User entered 'estradiol'	Dhwani Shah (b) (4)	19 Oct 2020 16:54:24

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:16:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:54:24

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:16:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered 'post menopause symptoms'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:54:24

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:16:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered '1'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:54:24

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:16:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered 'mg (mg)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:54:24

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:16:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:54:24

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:16:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered 'once daily (QD)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:54:24

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:16:08

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:54:24

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:16:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered 'Oral (ORAL)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:54:24

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:16:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:54:24

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:16:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered 'un UNK 2018'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:54:24

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:16:08

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:54:24

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:16:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:54:24

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:54:24

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:16:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:54:24

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:16:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 16:54:24

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:16:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 16:54:24

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 08:16:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Oct 2020 16:54:24

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:16:08

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: PROGESTOGENS, ATC: PREGNEN (4) DERIVATIVES, PRODUCT: PROGESTERONE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	19 Oct 2020 17:18:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	19 Oct 2020 17:18:57
Data point term sent to Coder	System	19 Oct 2020 16:55:07
User entered 'progesterone'	Dhwani Shah (b) (4)	19 Oct 2020 16:54:54

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:16:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:54:54

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:16:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered 'post menopausal symptoms'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:54:54

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:16:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered '10'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:54:54

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:16:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered 'mg (mg)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:54:54

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:16:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:54:54

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:16:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered 'once daily (QD)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:54:54

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:16:08

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:54:54

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:16:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered 'Oral (ORAL)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:54:54

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:16:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:54:54

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:16:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered 'un UNK 2018'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:54:54

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:16:08

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:54:54

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:16:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:54:54

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:54:54

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:16:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:54:54

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:16:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 16:54:54

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:16:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 16:54:54

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 08:16:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Oct 2020 16:54:54

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:16:08

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	19 Oct 2020 17:19:04
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	19 Oct 2020 17:19:04
Data point term sent to Coder	System	19 Oct 2020 16:56:08
User entered 'cetirizine'	Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:55:22

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:16:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:55:22

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:16:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
Query 'Per DM CLR: Please update the indication to reflect the type of SEASONAL ALLERGIES. Review and update indication and ensure to update MH eCRF as appropriate. ' canceled (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 22:17:19
User opened query 'Per DM CLR: Please update the indication to reflect the type of SEASONAL ALLERGIES. Review and update indication and ensure to update MH eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 15:02:24
User entered 'seasonal allergies'	Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:55:22

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:16:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered '10'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:55:22

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:16:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered 'mg (mg)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:55:22

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:16:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:55:22

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:16:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered 'as needed (PRN)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:55:22

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:16:08

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:55:22

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:16:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered 'Oral (ORAL)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:55:22

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:16:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:55:22

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:16:08

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered 'un UNK 2010'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:55:22

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:16:08

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:55:22

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:16:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:55:22

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:55:22

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:16:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	19 Oct 2020 16:55:22

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:16:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 16:55:22

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:16:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 16:55:22

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 08:16:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 16:55:22

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:16:08

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	21 Apr 2021 22:13:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	21 Apr 2021 22:13:42
Data point term sent to Coder User entered 'ASPIRIN'	System Dhwani Shah (b) (4)	21 Apr 2021 22:12:39 21 Apr 2021 22:12:38

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:16:08

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	21 Apr 2021 22:12:38

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:16:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
User entered 'CARDIAC PROPHYLAXIS'	(b) (4) Dhwani Shah (b) (4) (b) (4)	21 Apr 2021 22:12:38

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:16:08

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
User entered '81'	(b) (4) Dhwani Shah (b) (4) (b) (4)	21 Apr 2021 22:12:38

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:16:08

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
User entered 'mg (mg)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	21 Apr 2021 22:12:38

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:16:08

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	21 Apr 2021 22:12:38

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:16:08

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
User entered 'once daily (QD)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	21 Apr 2021 22:12:38

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:16:08

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	21 Apr 2021 22:12:38

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:16:08

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
User entered 'Oral (ORAL)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	21 Apr 2021 22:12:38

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:16:08

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	21 Apr 2021 22:12:38

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:16:08

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
User entered '16 Apr 2021'	(b) (4) Dhwani Shah (b) (4) (b) (4)	21 Apr 2021 22:12:38

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:16:08

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
User entered '0'	(b) (4) Dhwani Shah (b) (4) (b) (4)	21 Apr 2021 22:12:38

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:16:08

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
User entered 'Yes (Y)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	21 Apr 2021 22:12:38

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:16:08

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

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	21 Apr 2021 22:12:38

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:16:08

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	21 Apr 2021 22:12:38

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:16:08

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 22:12:38

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:16:08

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 22:12:38

US3562229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 08:16:08

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Apr 2021 22:12:38

US3562229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 08:16:08

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:03:58
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
Signature has been broken.	(b) (4) Dhwani Shah (b) (4)	21 Apr 2021 22:08:52
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Dhwani Shah (b) (4)	21 Apr 2021 22:08:52
User signature succeeded.	(b) (4) Joseph Davis (b) (4)	08 Apr 2021 22:10:23
User entered 'No (N)'	(b) (4) Dhwani Shah (b) (4)	19 Oct 2020 16:48:22

US3562229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:16:08

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
User entered '17 Apr 2021'	(b) (4) Dhwani Shah (b) (4) (b) (4)	21 Apr 2021 22:10:24

US3562229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:16:08

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
User entered 'MRI BRAIN'	(b) (4) Dhwani Shah (b) (4) (b) (4)	21 Apr 2021 22:10:24

US3562229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:16:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
User entered 'Adverse Event (AE)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	21 Apr 2021 22:10:24

US3562229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 08:16:08

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	21 Apr 2021 22:10:24

US3562229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:16:08

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
User entered '17 Apr 2021'	(b) (4) Dhwani Shah (b) (4) (b) (4)	21 Apr 2021 22:10:37

US3562229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:16:08

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
User entered 'MRI C-SPINE'	(b) (4) Dhwani Shah (b) (4) (b) (4)	21 Apr 2021 22:10:37

US3562229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:16:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
User entered 'Adverse Event (AE)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	21 Apr 2021 22:10:37

US3562229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 08:16:08

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
	(b) (4)	
User entered empty.	Dhwani Shah (b) (4)	21 Apr 2021 22:10:37
	(b) (4)	

US3562229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:16:08

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
User entered '16 Apr 2021'	(b) (4) Dhwani Shah (b) (4) (b) (4)	21 Apr 2021 22:10:51

US3562229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:16:08

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
User entered 'X-RAY CHEST 1 VIEW'	(b) (4) Dhwani Shah (b) (4) (b) (4)	21 Apr 2021 22:10:51

US3562229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:16:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
User entered 'Adverse Event (AE)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	21 Apr 2021 22:10:51

US3562229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 08:16:08

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
	(b) (4)	
User entered empty.	Dhwani Shah (b) (4)	21 Apr 2021 22:10:51
	(b) (4)	

US3562229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:16:08

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
User entered '16 Apr 2021'	(b) (4) Dhwani Shah (b) (4) (b) (4)	21 Apr 2021 22:11:16

US3562229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:16:08

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
User entered 'CT ANGIO HEAD/NECK'	(b) (4) Dhwani Shah (b) (4) (b) (4)	21 Apr 2021 22:11:16

US3562229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:16:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
User entered 'Adverse Event (AE)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	21 Apr 2021 22:11:16

US3562229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 08:16:08

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	21 Apr 2021 22:11:16

US3562229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 08:16:08

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
User entered '16 Apr 2021'	(b) (4) Dhwani Shah (b) (4) (b) (4)	21 Apr 2021 22:11:34

US3562229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 08:16:08

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
User entered 'ELECTROCARDIOGRAM'	(b) (4) Dhwani Shah (b) (4) (b) (4)	21 Apr 2021 22:11:34

US3562229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 08:16:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
User entered 'Adverse Event (AE)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	21 Apr 2021 22:11:34

US3562229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 08:16:08

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	21 Apr 2021 22:11:34

US3562229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 08:16:08

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
User entered '18 Apr 2021'	(b) (4) Dhwani Shah (b) (4) (b) (4)	21 Apr 2021 22:11:55

US3562229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 08:16:08

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
User entered 'XR SWALLOW FUNCTION VIDEO OR CLINE'	(b) (4) Dhwani Shah (b) (4)	21 Apr 2021 22:11:55

US3562229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 08:16:08

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
User entered 'Adverse Event (AE)'	(b) (4) Dhwani Shah (b) (4) (b) (4)	21 Apr 2021 22:11:55

US3562229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 08:16:08

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
User entered empty.	(b) (4) Dhwani Shah (b) (4) (b) (4)	21 Apr 2021 22:11:55

US3562229

Folder: SAE USA-US071-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:08

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:07:26
User entered 'USA-US071-2021-MRNA-1273-P301000007'	System	22 Apr 2021 15:03:04

US3562229

Folder: SAE USA-US071-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:08

Serious

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
Reviewed for Safety.	(b) (4)	22 Apr 2021 15:07:26
User entered 'Yes (Y)'	(b) (4), (b) (6) System	22 Apr 2021 15:03:04

US3562229

Folder: SAE USA-US071-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:08

Death

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:07:26
User entered 'No (N)'	System	22 Apr 2021 15:03:04

US3562229

Folder: SAE USA-US071-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:08

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:07:26
User entered 'No (N)'	System	22 Apr 2021 15:03:04

US3562229

Folder: SAE USA-US071-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
Reviewed for Safety.	(b) (4)	22 Apr 2021 15:07:26
User entered 'Yes (Y)'	(b) (4), (b) (6) System	22 Apr 2021 15:03:04

US3562229

Folder: SAE USA-US071-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:07:26
User entered 'No (N)'	System	22 Apr 2021 15:03:04

US3562229

Folder: SAE USA-US071-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:07:26
User entered 'No (N)'	System	22 Apr 2021 15:03:04

US3562229

Folder: SAE USA-US071-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:08

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:07:26
User entered 'No (N)'	System	22 Apr 2021 15:03:04

US3562229

Folder: SAE USA-US071-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:08

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:07:26
User entered 'Joseph'	System	22 Apr 2021 15:03:04

US3562229

Folder: SAE USA-US071-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:08

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:07:26
User entered 'Davis'	System	22 Apr 2021 15:03:04

US3562229

Folder: SAE USA-US071-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:08

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:07:26
User entered '3900 E Camel Back road'	System	22 Apr 2021 15:03:04

US3562229

Folder: SAE USA-US071-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:08

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:07:26
User entered 'Phoenix'	System	22 Apr 2021 15:03:04

US3562229

Folder: SAE USA-US071-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:08

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:07:26
User entered '85018'	System	22 Apr 2021 15:03:04

US3562229

Folder: SAE USA-US071-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:08

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:24:49
User entered 'US'	System	22 Apr 2021 15:07:34

US3562229

Folder: SAE USA-US071-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:08

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	22 Apr 2021 15:26:05
User entered '1'	System	22 Apr 2021 15:07:34

US3562229

Folder: SAE USA-US071-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:08

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:07:26
User entered 'USA-US071-2021-MRNA-1273-P301000007'	System	22 Apr 2021 15:03:04

US3562229

Folder: SAE USA-US071-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:08

Serious

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:07:26
User entered 'Yes (Y)'	System	22 Apr 2021 15:03:04

US3562229

Folder: SAE USA-US071-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:08

Death

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:07:26
User entered 'No (N)'	System	22 Apr 2021 15:03:04

US3562229

Folder: SAE USA-US071-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:08

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:07:26
User entered 'No (N)'	System	22 Apr 2021 15:03:04

US3562229

Folder: SAE USA-US071-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
Reviewed for Safety.	(b) (4)	22 Apr 2021 15:07:26
User entered 'Yes (Y)'	(b) (4), (b) (6) System	22 Apr 2021 15:03:04

US3562229

Folder: SAE USA-US071-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
Reviewed for Safety.	(b) (4)	22 Apr 2021 15:07:26
User entered 'No (N)'	(b) (4), (b) (6) System	22 Apr 2021 15:03:04

US3562229

Folder: SAE USA-US071-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:07:26
User entered 'No (N)'	System	22 Apr 2021 15:03:04

US3562229

Folder: SAE USA-US071-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:08

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:07:26
User entered 'No (N)'	System	22 Apr 2021 15:03:04

US3562229

Folder: SAE USA-US071-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:08

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:07:26
User entered 'Joseph'	System	22 Apr 2021 15:03:04

US3562229

Folder: SAE USA-US071-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:08

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:07:26
User entered 'Davis'	System	22 Apr 2021 15:03:04

US3562229

Folder: SAE USA-US071-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:08

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:07:26
User entered '3900 E Camel Back road'	System	22 Apr 2021 15:03:04

US3562229

Folder: SAE USA-US071-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:08

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:07:26
User entered 'Phoenix'	System	22 Apr 2021 15:03:04

US3562229

Folder: SAE USA-US071-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:08

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:07:26
User entered '85018'	System	22 Apr 2021 15:03:04

US3562229

Folder: SAE USA-US071-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:08

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:24:49
User entered 'US'	System	22 Apr 2021 15:07:34

US3562229

Folder: SAE USA-US071-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:08

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	22 Apr 2021 15:26:05
User entered '1'	System	22 Apr 2021 15:07:34

US3562229

Folder: SAE USA-US071-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:16:08

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
User entered '22/Apr/2021 11:07'	(b) (4) System	22 Apr 2021 15:07:34

US3562229

Folder: SAE USA-US071-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 08:16:08

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.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:24:49
User entered 'l'		22 Apr 2021 15:07:34

US3562229

Folder: SAE USA-US071-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:08

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:07:26
User entered 'USA-US071-2021-MRNA-1273-P301000007'	System	22 Apr 2021 15:03:04

US3562229

Folder: SAE USA-US071-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:08

Serious

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:07:26
User entered 'Yes (Y)'	System	22 Apr 2021 15:03:04

US3562229

Folder: SAE USA-US071-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:08

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:07:26
User entered 'No (N)'	System	22 Apr 2021 15:03:04

US3562229

Folder: SAE USA-US071-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:08

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 15:07:26
User entered 'No (N)'	System	22 Apr 2021 15:03:04

US3562229

Folder: SAE USA-US071-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:08

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:07:26
User entered 'Yes (Y)'	System	22 Apr 2021 15:03:04

US3562229

Folder: SAE USA-US071-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:08

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:07:26
User entered 'No (N)'	System	22 Apr 2021 15:03:04

US3562229

Folder: SAE USA-US071-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:08

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:07:26
User entered 'No (N)'	System	22 Apr 2021 15:03:04

US3562229

Folder: SAE USA-US071-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:08

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
Reviewed for Safety.	(b) (4)	22 Apr 2021 15:07:26
User entered 'No (N)'	(b) (4), (b) (6) System	22 Apr 2021 15:03:04

US3562229

Folder: SAE USA-US071-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:08

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:07:26
User entered 'Joseph'	System	22 Apr 2021 15:03:04

US3562229

Folder: SAE USA-US071-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:08

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
Reviewed for Safety.	(b) (4)	22 Apr 2021 15:07:26
User entered 'Davis'	(b) (4), (b) (6) System	22 Apr 2021 15:03:04

US3562229

Folder: SAE USA-US071-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:08

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:07:26
User entered '3900 E Camel Back road'	System	22 Apr 2021 15:03:04

US3562229

Folder: SAE USA-US071-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:08

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:07:26
User entered 'Phoenix'	System	22 Apr 2021 15:03:04

US3562229

Folder: SAE USA-US071-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:08

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
Reviewed for Safety.	(b) (4)	22 Apr 2021 15:07:26
User entered '85018'	(b) (4), (b) (6) System	22 Apr 2021 15:03:04

US3562229

Folder: SAE USA-US071-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:08

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:24:49
User entered 'US'	System	22 Apr 2021 15:07:34

US3562229

Folder: SAE USA-US071-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 10 Jun 2021 08:16:08

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	22 Apr 2021 15:26:05
User entered '1'	System	22 Apr 2021 15:07:34

US3562229

Folder: SAE USA-US071-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:16:08

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
User entered '22/Apr/2021 11:26'	(b) (4) System	22 Apr 2021 15:26:05

US3562229

Folder: SAE USA-US071-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 08:16:08

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.	Joseph Davis (b) (4)	23 Apr 2021 20:18:00
User entered 'I'	(b) (4) (b) (4), (b) (6)	22 Apr 2021 15:26:05