

US3182065 (Prod: Rapid Medical Research Inc - ERN-PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:38:18

All time stamps listed in this document are displayed in GMT

US3182065

Form: Participant Creation

Data signed: (b) (4) 09 Mar 2021 04:06:44

Generated On: 09 Jun 2021 15:38:18

[Participant ID](#)

US3182065

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

US3182065

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 19:34:22

Generated On: 09 Jun 2021 15:38:18

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

US3182065

Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 19:34:21

Generated On: 09 Jun 2021 15:38:18

Date of Birth (MMM yyyy)	(b) (6) 1960
Age	60
Age Units	YEARS
Age (Derived)	60
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 19:34:21

Generated On: 09 Jun 2021 15:38:18

Date of Informed Consent (*dd MMM yyyy*) 29 JUL 2020

Month and Year of Informed Consent (derived) JUL 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

US3182065

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 19:34:21

Generated On: 09 Jun 2021 15:38:18

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 19:34:21

Generated On: 09 Jun 2021 15:38:18

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 15 Feb 2021 19:34:21

Generated On: 09 Jun 2021 15:38:18

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1974
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 1974
Start Year (derived)	1974
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Feb 2021 19:34:21

Generated On: 09 Jun 2021 15:38:18

Condition	TONSILLECTOMY
Start date (dd MMM yyyy)	UN UNK 1966
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1966
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1966
Start Year (derived)	1966
Stop Month and Year (derived)	JAN 1966
Stop Year (derived)	1966

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 15 Feb 2021 19:34:21

Generated On: 09 Jun 2021 15:38:18

Condition	BILATERAL MYOPIA
Start date (dd MMM yyyy)	UN UNK 1973
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 1973
Start Year (derived)	1973
Stop Month and Year (derived)	
Stop Year (derived)	

US3182065

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 15 Feb 2021 19:34:21

Generated On: 09 Jun 2021 15:38:18

Condition	TONSILLITIS
Start date (dd MMM yyyy)	UN UNK 1966
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1966
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1966
Start Year (derived)	1966
Stop Month and Year (derived)	JAN 1966
Stop Year (derived)	1966

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 19:34:22

Generated On: 09 Jun 2021 15:38:18

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	29 JUL 2020
Time of assessment (<i>00:00-23:59</i>)	15:33 (24 HR)
Vital Signs Date and Time (derived)	29 JUL 2020 15:33
Height (<i>xxx.x</i>)	166.0 cm
Weight (<i>xxx.x</i>)	66.2 kg
BMI (<i>xxx.x</i>)	24.02381 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) 15 Feb 2021 19:34:21

Generated On: 09 Jun 2021 15:38:18

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 JUL 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 15 Feb 2021 19:34:21

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Date of assessment (dd MMM yyyy) 29 JUL 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 2009

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 19:34:22

Generated On: 09 Jun 2021 15:38:18

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 True

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 19:34:22

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 19:05:26

Generated On: 09 Jun 2021 15:38:18

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 JUL 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 19:05:26

Generated On: 09 Jun 2021 15:38:18

What was the date of randomization? (dd MMM yyyy) 29 JUL 2020

What was the participant's randomization number? 142290

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 ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 19:05:26

Generated On: 09 Jun 2021 15:38:18

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 19:05:26

Generated On: 09 Jun 2021 15:38:18

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	29 JUL 2020
Time of assessment (00:00-23:59)	15:33 (24 HR)
Vital Signs Date and Time (derived)	29 JUL 2020 15:33
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 19:05:26

Generated On: 09 Jun 2021 15:38:18

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	29 JUL 2020
Time of assessment (00:00-23:59)	17:02 (24 HR)
Vital Signs Date and Time (derived)	29 JUL 2020 17:02
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 19:05:26

Generated On: 09 Jun 2021 15:38:18

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 19:05:26

Generated On: 09 Jun 2021 15:38:18

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 29 JUL 2020

What was the treatment time? (00:00-23:59) 16:27 (24 HR)

Treatment Date and Time (derived) 29 JUL 2020 16:27

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 19:05:26

Generated On: 09 Jun 2021 15:38:18

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

Collection date (dd MMM yyyy)	29 JUL 2020
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Collection time (00:00-23:59)	15:35 (24 HR)
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Collection date and time (derived)	29 JUL 2020 15:35
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US3182065

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 19:05:25

Generated On: 09 Jun 2021 15:38:18

Collection date (dd MMM yyyy)			29 JUL 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:50	29 JUL 2020 15:50
Nasopharyngeal Swab 2	No		

US3182065

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 19:05:25

Generated On: 09 Jun 2021 15:38:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:38:18

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

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

Yes ☐
No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

29 JUL 2020 16:47

PC Close Date & Time

29 JUL 2020 19:17

US3182065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☐
No ☐

Please record your **TEMPERATURE** in °F

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 29 JUL 2020 20:12

PC Close Date & Time 30 JUL 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

30 JUL 2020 12:00

PC Close Date & Time

31 JUL 2020 11:59

US3182065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 JUL 2020 18:31

PC Open Date & Time

31 JUL 2020 12:00

PC Close Date & Time

01 AUG 2020 11:59

US3182065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 AUG 2020 19:22

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 AUG 2020 13:07

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3182065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 AUG 2020 18:20

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3182065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 AUG 2020 23:56

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3182065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:38:18

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

29 JUL 2020 16:47

PC Close Date & Time

29 JUL 2020 19:17

US3182065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

29 JUL 2020 20:12

PC Close Date & Time

30 JUL 2020 11:59

US3182065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

30 JUL 2020 12:00

PC Close Date & Time

31 JUL 2020 11:59

US3182065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

31 JUL 2020 18:32

PC Open Date & Time

31 JUL 2020 12:00

PC Close Date & Time

01 AUG 2020 11:59

US3182065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 AUG 2020 19:23

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3182065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 AUG 2020 13:07

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3182065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 AUG 2020 18:21

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3182065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 AUG 2020 23:56

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:38:18

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 ☐

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:38:18

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

29 JUL 2020 16:47

PC Close Date & Time

29 JUL 2020 19:17

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:38:18

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 ☐

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:38:18

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

29 JUL 2020 20:12

PC Close Date & Time

30 JUL 2020 11:59

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:38:18

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 ☐

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:38:18

Yes ☐

PC Time stamp

PC Open Date & Time

30 JUL 2020 12:00

PC Close Date & Time

31 JUL 2020 11:59

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:38:18

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 ☒

PRODUCTION RELEASE (v12.003

48 of 2079

EAB) (1725)

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:38:18

Yes <input type="checkbox"/>	
PC Time stamp	31 JUL 2020 18:32
PC Open Date & Time	31 JUL 2020 12:00
PC Close Date & Time	01 AUG 2020 11:59

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

50 of 2079

EAB) (1725)

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:38:18

Yes <input type="checkbox"/>	
PC Time stamp	01 AUG 2020 19:23
PC Open Date & Time	01 AUG 2020 12:00
PC Close Date & Time	02 AUG 2020 11:59

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:38:18

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 ☒

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:38:18

Yes <input type="checkbox"/>	
PC Time stamp	02 AUG 2020 13:07
PC Open Date & Time	02 AUG 2020 12:00
PC Close Date & Time	03 AUG 2020 11:59

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:38:18

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 ☒

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:38:18

Yes <input type="checkbox"/>	
PC Time stamp	03 AUG 2020 18:21
PC Open Date & Time	03 AUG 2020 12:00
PC Close Date & Time	04 AUG 2020 11:59

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:38:18

Yes <input type="checkbox"/>	
PC Time stamp	04 AUG 2020 23:57
PC Open Date & Time	04 AUG 2020 12:00
PC Close Date & Time	05 AUG 2020 11:59

US3182065

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 17:59:19

Generated On: 09 Jun 2021 15:38:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3182065

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 17:59:19

Generated On: 09 Jun 2021 15:38:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182065

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 17:59:19

Generated On: 09 Jun 2021 15:38:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3182065

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 17:59:19

Generated On: 09 Jun 2021 15:38:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182065

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 17:59:19

Generated On: 09 Jun 2021 15:38:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3182065

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 17:59:19

Generated On: 09 Jun 2021 15:38:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182065

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 19:05:26

Generated On: 09 Jun 2021 15:38:18

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3182065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 19:05:26

Generated On: 09 Jun 2021 15:38:18

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)	28 AUG 2020
Time of assessment (00:00-23:59)	11:25 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 11:25
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	94 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3182065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 19:05:26

Generated On: 09 Jun 2021 15:38:18

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)	28 AUG 2020
Time of assessment (00:00-23:59)	12:34 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 12:34
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	83 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3182065

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 19:05:26

Generated On: 09 Jun 2021 15:38:18

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 AUG 2020

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

US3182065

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 19:05:26

Generated On: 09 Jun 2021 15:38:18

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) 28 AUG 2020

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

Treatment Date and Time (derived) 28 AUG 2020 11:59

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

What was the frequency of the study treatment dosing? ONCE

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

US3182065

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 19:05:26

Generated On: 09 Jun 2021 15:38:18

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

28 AUG 2020

Collection time (00:00-23:59)

11:44 (24 HR)

Collection date and time (derived)

28 AUG 2020 11:44

US3182065

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 19:05:26

Generated On: 09 Jun 2021 15:38:18

Collection date (dd MMM yyyy)			28 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:40	28 AUG 2020 11:40
Nasopharyngeal Swab 2	No		

US3182065

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 19:05:26

Generated On: 09 Jun 2021 15:38:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐
No ☒

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

PC Time Stamp 28 AUG 2020 12:36

PC Open Date & Time 28 AUG 2020 12:19

PC Close Date & Time 28 AUG 2020 14:49

US3182065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 96.5 °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	28 AUG 2020 21:29
PC Open Date & Time	28 AUG 2020 15:44
PC Close Date & Time	29 AUG 2020 11:59

US3182065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 AUG 2020 23:56

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3182065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.1 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

30 AUG 2020 18:54

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3182065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

31 AUG 2020 23:48

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3182065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

02 SEP 2020 04:06

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3182065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

95.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 00:06

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3182065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 16:05

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3182065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 AUG 2020 12:36

PC Open Date & Time

28 AUG 2020 12:19

PC Close Date & Time

28 AUG 2020 14:49

US3182065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:38:18

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

28 AUG 2020 21:29

PC Open Date & Time

28 AUG 2020 15:44

PC Close Date & Time

29 AUG 2020 11:59

US3182065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 AUG 2020 23:56

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3182065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 AUG 2020 18:54

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3182065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

31 AUG 2020 23:49

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3182065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 SEP 2020 04:06

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3182065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 00:06

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3182065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 16:05

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:38:18

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 ☐

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:38:18

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

No ☒

Yes ☐

PC Time stamp	28 AUG 2020 12:37
PC Open Date & Time	28 AUG 2020 12:19
PC Close Date & Time	28 AUG 2020 14:49

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:38:18

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 ☐

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:38:18

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

No ☒

Yes ☐

PC Time stamp	28 AUG 2020 21:30
PC Open Date & Time	28 AUG 2020 15:44
PC Close Date & Time	29 AUG 2020 11:59

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:38:18

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 ☒

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:38:18

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 23:57
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:38:18

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 ☒

PRODUCTION RELEASE (v12.003

94 of 2079

EAB) (1725)

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:38:18

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 18:55
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

96 of 2079

EAB) (1725)

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:38:18

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 23:49
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:38:18

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 ☒

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:38:18

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 04:07
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:38:18

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 00:06
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

102 of 2079

EAB) (1725)

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:38:18

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 16:05
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3182065

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 17:59:19

Generated On: 09 Jun 2021 15:38:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3182065

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 17:59:19

Generated On: 09 Jun 2021 15:38:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182065

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 19:05:25

Generated On: 09 Jun 2021 15:38:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3182065

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 19:05:25

Generated On: 09 Jun 2021 15:38:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182065

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 19:05:25

Generated On: 09 Jun 2021 15:38:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3182065

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 19:05:25

Generated On: 09 Jun 2021 15:38:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182065

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 19:05:26

Generated On: 09 Jun 2021 15:38:18

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3182065

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 19:05:26

Generated On: 09 Jun 2021 15:38:18

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	23 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	11:05 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 11:05
Temperature (<i>xxx.x</i>)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	83 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	84 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3182065

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 19:05:26

Generated On: 09 Jun 2021 15:38:18

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.

US3182065

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 19:05:26

Generated On: 09 Jun 2021 15:38:18

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

Collection date (dd MMM yyyy)	23 SEP 2020
-------------------------------	-------------

Collection time (00:00-23:59)	11:08 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	23 SEP 2020 11:08
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US3182065

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 19:05:26

Generated On: 09 Jun 2021 15:38:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2020 00:01

Patient Cloud Close Date & Time

02 OCT 2020 23:59

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2020 00:01

Patient Cloud Close Date & Time

09 OCT 2020 23:59

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2020 00:01

Patient Cloud Close Date & Time

16 OCT 2020 23:59

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 OCT 2020 00:02:17
Patient Cloud Open Date & Time	26 OCT 2020 00:01
Patient Cloud Close Date & Time	30 OCT 2020 23:59

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 NOV 2020 02:47:16
Patient Cloud Open Date & Time	02 NOV 2020 00:01
Patient Cloud Close Date & Time	06 NOV 2020 23:59

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

DAY 106

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 NOV 2020 10:23:20

Patient Cloud Open Date & Time

09 NOV 2020 00:01

Patient Cloud Close Date & Time

13 NOV 2020 23:59

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT	DAY 113
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	17 NOV 2020 04:17:47
Patient Cloud Open Date & Time	16 NOV 2020 00:01
Patient Cloud Close Date & Time	20 NOV 2020 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 NOV 2020 11:42:14

Patient Cloud Open Date & Time

20 NOV 2020 00:01

Patient Cloud Close Date & Time

24 NOV 2020 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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	01 DEC 2020 07:06:01
Patient Cloud Open Date & Time	27 NOV 2020 00:01
Patient Cloud Close Date & Time	01 DEC 2020 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 DEC 2020 03:34:35

Patient Cloud Open Date & Time

04 DEC 2020 00:01

Patient Cloud Close Date & Time

08 DEC 2020 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 DEC 2020 06:57:54

Patient Cloud Open Date & Time

11 DEC 2020 00:01

Patient Cloud Close Date & Time

15 DEC 2020 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

20 DEC 2020 10:03:12

Patient Cloud Open Date & Time

18 DEC 2020 00:01

Patient Cloud Close Date & Time

22 DEC 2020 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 DEC 2020 20:04:25

Patient Cloud Open Date & Time

25 DEC 2020 00:01

Patient Cloud Close Date & Time

29 DEC 2020 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 JAN 2021 16:03:08

Patient Cloud Open Date & Time

01 JAN 2021 00:01

Patient Cloud Close Date & Time

05 JAN 2021 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

[Patient Cloud Close Date & Time](#)

12 JAN 2021 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 JAN 2021 22:36:55

Patient Cloud Open Date & Time

15 JAN 2021 00:01

Patient Cloud Close Date & Time

19 JAN 2021 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 JAN 2021 06:54:00

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

DAY 187

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

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

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

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

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

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

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 ☐

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	29 JAN 2021 00:01
Patient Cloud Close Date & Time	02 FEB 2021 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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 type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	08 FEB 2021 08:47:37
Patient Cloud Open Date & Time	05 FEB 2021 00:01
Patient Cloud Close Date & Time	09 FEB 2021 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

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 ☐

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

[Patient Cloud Open Date & Time](#)

19 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2021 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 FEB 2021 18:32:44

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 MAR 2021 02:34:25

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2021 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2021 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 MAR 2021 10:16:28

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 APR 2021 16:01:08

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 APR 2021 13:57:43

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 APR 2021 00:01
Patient Cloud Close Date & Time	20 APR 2021 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	23 APR 2021 00:01
Patient Cloud Close Date & Time	27 APR 2021 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

[Patient Cloud Open Date & Time](#)

30 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2021 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

DAY 285

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

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

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

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

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

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

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

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

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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 ☐

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 MAY 2021 00:01
Patient Cloud Close Date & Time	25 MAY 2021 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

DAY 313

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

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

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

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

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

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

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

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

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

DAY 327

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

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

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

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

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

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

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

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

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

[Patient Cloud Open Date & Time](#)

25 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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 ☐

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

[Patient Cloud Open Date & Time](#)

23 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

DAY 376

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

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

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

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

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

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

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

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

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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 ☐

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2021 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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 ☐

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

[Patient Cloud Open Date & Time](#)

20 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	27 AUG 2021 00:01
Patient Cloud Close Date & Time	31 AUG 2021 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

DAY 418

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

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

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

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

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

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

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

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

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

Patient Cloud Open Date & Time	17 SEP 2021 00:01
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Patient Cloud Close Date & Time	21 SEP 2021 23:59
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US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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 ☐

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

[Patient Cloud Open Date & Time](#)

24 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

DAY 432

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

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

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

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

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

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

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

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

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

DAY 439

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

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

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

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

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

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

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

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

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

19 OCT 2021 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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 ☐

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 OCT 2021 00:01
Patient Cloud Close Date & Time	26 OCT 2021 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

[Patient Cloud Open Date & Time](#)

29 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

DAY 467

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

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

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

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

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

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

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

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

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

[Patient Cloud Open Date & Time](#)

05 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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 ☐

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

[Patient Cloud Open Date & Time](#)

03 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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 ☐

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

14 DEC 2021 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

DAY 509

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

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

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

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

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

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

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

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

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

[Patient Cloud Open Date & Time](#)

24 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

28 DEC 2021 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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 ☐

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

DAY 530

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

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

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

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

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

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

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

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

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

[Patient Cloud Open Date & Time](#)

07 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

DAY 551

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

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

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

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

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

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

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

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

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

[Patient Cloud Open Date & Time](#)

28 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

[Patient Cloud Open Date & Time](#)

04 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

DAY 565

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

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

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

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

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

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

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

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

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

[Patient Cloud Open Date & Time](#)

11 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

DAY 579

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

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

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

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

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

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

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

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

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

[Patient Cloud Open Date & Time](#)

25 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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 ☐

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

[Patient Cloud Open Date & Time](#)

04 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

[Patient Cloud Open Date & Time](#)

11 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

[Patient Cloud Open Date & Time](#)

25 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

[Patient Cloud Open Date & Time](#)

01 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

[Patient Cloud Open Date & Time](#)

08 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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 ☐

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

[Patient Cloud Open Date & Time](#)

15 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2022 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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 ☐

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 APR 2022 00:01
Patient Cloud Close Date & Time	26 APR 2022 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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 ☐

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

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 ☐

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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 ☐

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

DAY 663

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

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

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

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

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

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

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

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

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

[Patient Cloud Open Date & Time](#)

20 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

[Patient Cloud Open Date & Time](#)

27 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

[Patient Cloud Open Date & Time](#)

03 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

[Patient Cloud Open Date & Time](#)

10 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

[Patient Cloud Open Date & Time](#)

17 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

DAY 698

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

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

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

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

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

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

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

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

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

[Patient Cloud Open Date & Time](#)

24 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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 ☐

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	08 JUL 2022 00:01
Patient Cloud Close Date & Time	12 JUL 2022 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 JUL 2022 00:01
Patient Cloud Close Date & Time	19 JUL 2022 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 JUL 2022 00:01
Patient Cloud Close Date & Time	26 JUL 2022 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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 ☐

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

[Patient Cloud Open Date & Time](#)

05 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

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 ☐

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

[Patient Cloud Open Date & Time](#)

12 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2022 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

Patient Cloud Open Date & Time	26 AUG 2022 00:01
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Patient Cloud Close Date & Time	30 AUG 2022 23:59
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US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

[Patient Cloud Open Date & Time](#)

02 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

[Patient Cloud Open Date & Time](#)

09 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

[Patient Cloud Open Date & Time](#)

16 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

Date and time of submission

Patient Cloud Open Date & Time	23 SEP 2022 00:01
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Patient Cloud Close Date & Time	27 SEP 2022 23:59
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US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

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

[Patient Cloud Open Date & Time](#)

30 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3182065

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:38:18

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
Yes	No	28 FEB 2021 18:32:57

US3182065

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 04:07:04

Generated On: 09 Jun 2021 15:38:18

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

US3182065

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 04:07:04

Generated On: 09 Jun 2021 15:38:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182065

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 04:07:04

Generated On: 09 Jun 2021 15:38:18

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

US3182065

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 04:07:04

Generated On: 09 Jun 2021 15:38:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182065

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 04:07:04

Generated On: 09 Jun 2021 15:38:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3182065

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 04:07:04

Generated On: 09 Jun 2021 15:38:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182065

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 04:07:04

Generated On: 09 Jun 2021 15:38:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3182065

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 04:07:04

Generated On: 09 Jun 2021 15:38:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182065

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 10 Mar 2021 21:44:32

Generated On: 09 Jun 2021 15:38:18

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3182065

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 31 Mar 2021 14:53:04

Generated On: 09 Jun 2021 15:38:18

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	24 FEB 2021
Time of assessment (00:00-23:59)	16:07 (24 HR)
Vital Signs Date and Time (derived)	24 FEB 2021 16:07
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	94 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3182065

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 31 Mar 2021 14:53:04

Generated On: 09 Jun 2021 15:38:18

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 FEB 2021

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

US3182065

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 10 Mar 2021 21:44:32

Generated On: 09 Jun 2021 15:38:18

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

Collection date (dd MMM yyyy)	24 FEB 2021
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Collection time (00:00-23:59)	15:55 (24 HR)
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Collection date and time (derived)	24 FEB 2021 15:55
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US3182065

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 21:44:32

Generated On: 09 Jun 2021 15:38:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182065

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 30 Mar 2021 18:05:20

Generated On: 09 Jun 2021 15:38:18

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 29 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3182065

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 30 Mar 2021 18:05:20

Generated On: 09 Jun 2021 15:38:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182065

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:18

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

US3182065

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:38:18

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3182065

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:38:18

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"/>

US3182065

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:38:18

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3182065

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

Form: Visit Date

Data signed: (b) (4) 09 Mar 2021 04:07:04

Generated On: 09 Jun 2021 15:38:18

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

Visit date (dd MMM yyyy)	14 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3182065

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

Form: Unblinding

Data signed: (b) (4) 09 Mar 2021 04:07:04

Generated On: 09 Jun 2021 15:38:18

Date of updated informed consent (<i>dd MMM yyyy</i>)	14 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 type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	14 JAN 2021
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

US3182065

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 09 Mar 2021 04:07:04

Generated On: 09 Jun 2021 15:38:18

Height	166.0 cm
Weight	66.2 kg
BMI (xxx.x)	24.02381

US3182065

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 09 Mar 2021 04:07:04

Generated On: 09 Jun 2021 15:38:18

Height	166.0 cm
Weight	66.2 kg
BMI (xxx.x)	24.02381
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)	14 JAN 2021
Time of assessment (00:00-23:59)	14:00 (24 HR)
Vital Signs Date and Time (derived)	14 JAN 2021 14:00
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify _____	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3182065

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 09 Mar 2021 04:07:04

Generated On: 09 Jun 2021 15:38:18

Height	166.0 cm
Weight	66.2 kg
BMI (xxx.x)	24.02381
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)	14 JAN 2021
Time of assessment (00:00-23:59)	15:55 (24 HR)
Vital Signs Date and Time (derived)	14 JAN 2021 15:55
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3182065

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

Form: Physical Examination

Data signed: (b) (4) 09 Mar 2021 04:07:04

Generated On: 09 Jun 2021 15:38:18

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 JAN 2021

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

US3182065

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

Form: Exposure

Data signed: (b) (4) 09 Mar 2021 04:07:04

Generated On: 09 Jun 2021 15:38:18

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) 14 JAN 2021

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

Treatment Date and Time (derived) 14 JAN 2021 15:24

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

US3182065

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Mar 2021 04:07:04

Generated On: 09 Jun 2021 15:38:18

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

14 JAN 2021

Collection time (00:00-23:59)

13:45 (24 HR)

Collection date and time (derived)

14 JAN 2021 13:45

US3182065

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 09 Mar 2021 04:07:04

Generated On: 09 Jun 2021 15:38:18

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	14 JAN 2021
Collection time (00:00 - 23:59)	14:50
Collection Date and Time (derived)	14 JAN 2021 14:50

US3182065

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

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 04:07:04

Generated On: 09 Jun 2021 15:38:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182065

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 04:07:04

Generated On: 09 Jun 2021 15:38:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3182065

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 04:07:04

Generated On: 09 Jun 2021 15:38:18

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

US3182065

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 09 Mar 2021 04:06:44

Generated On: 09 Jun 2021 15:38:18

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3182065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 09 Mar 2021 04:06:44

Generated On: 09 Jun 2021 15:38:18

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)	24 FEB 2021
Time of assessment (00:00-23:59)	16:07 (24 HR)
Vital Signs Date and Time (derived)	24 FEB 2021 16:07
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	94 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3182065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 09 Mar 2021 04:06:44

Generated On: 09 Jun 2021 15:38:18

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)	24 FEB 2021
Time of assessment (00:00-23:59)	16:45 (24 HR)
Vital Signs Date and Time (derived)	24 FEB 2021 16:45
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	91 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3182065

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Mar 2021 04:06:44

Generated On: 09 Jun 2021 15:38:18

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 FEB 2021

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

US3182065

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 09 Mar 2021 04:06:44

Generated On: 09 Jun 2021 15:38:18

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) 24 FEB 2021

What was the treatment time? (00:00-23:59) 16:10 (24 HR)

Treatment Date and Time (derived) 24 FEB 2021 16:10

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

US3182065

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 04:06:44

Generated On: 09 Jun 2021 15:38:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182065

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 16 Mar 2021 17:00:00

Generated On: 09 Jun 2021 15:38:18

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3182065

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 16 Mar 2021 17:00:00

Generated On: 09 Jun 2021 15:38:18

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3182065

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 12:57:34

Generated On: 09 Jun 2021 15:38:18

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 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

US3182065

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Mar 2021 12:57:34

Generated On: 09 Jun 2021 15:38:18

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	24 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	14:45 (24 HR)
Vital Signs Date and Time (derived)	24 MAR 2021 14:45
Temperature (<i>xxx.x</i>)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	108 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	76 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3182065

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 12:57:34

Generated On: 09 Jun 2021 15:38:18

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 MAR 2021

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

US3182065

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Mar 2021 12:57:34

Generated On: 09 Jun 2021 15:38:18

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

US3182065

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 09 Mar 2021 04:06:44

Generated On: 09 Jun 2021 15:38:18

Did the participant experience any adverse events?

Yes ☒
No ☐

If Yes, enter details on the Adverse Events form.

US3182065

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Apr 2021 15:17:47

Generated On: 09 Jun 2021 15:38:18

AEID	USA-US075-2021-MRNA-1273-P30 1000006
Adverse event	STAGE 4 PANCREATIC CANCER.
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)	11 FEB 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 type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	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 (1)

Data signed: (b) (4) 23 Apr 2021 15:17:47

Generated On: 09 Jun 2021 15:38:18

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

US3182065

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Apr 2021 15:17:47

Generated On: 09 Jun 2021 15:38:18

SUBJECT CALLED IN AND INFORMED US THAT SHE WAS JUST RECENTLY DIAGNOSED WITH PANCREATIC CANCER ON 11-FEB-2021. SHE WAS SCHEDULED TO PRESENT TO THIS SITE ON THAT SAME EXACT DAY (02/11/2021), HOWEVER, IT WAS CANCELLED BECAUSE SHE WAS HAVING A LIVER BIOPSY PERFORMED. SUBJECT HAS ENROLLED INTO OPEN LABEL PHASE, AND RECEIVED THE FIRST DOSE OF THE MRNA-1273 VACCINE/IP ON 14-JAN-2021 AT THIS SITE, AND IS NOW DUE FOR HER SECOND DOSE/DAY-28 VISIT. SUBJECT HAS DIAGNOSED WITH SAGE 4 PANCREATIC CANCER AND STARTED CHEMOTHERAPY ON 3/17/2021. MEDICAL RECORDS ARE PENDING.

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)	

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 09 Mar 2021 04:06:44

Generated On: 09 Jun 2021 15:38:18

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

Yes ☒

No ☐

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

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 20 Apr 2021 13:55:48

Generated On: 09 Jun 2021 15:38:18

Name of Medication VITAMIN D

Prophylaxis Yes ☒
No ☐

Indication HEALTH MAINTENANCE

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 20 Apr 2021 13:55:48

Generated On: 09 Jun 2021 15:38:18

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 20 Apr 2021 13:55:48

Generated On: 09 Jun 2021 15:38:18

Name of Medication MOTRIN

Prophylaxis Yes ☐
No ☒

Indication HEADACHE

Dose per administration 400

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) 20 Apr 2021 13:55:48

Generated On: 09 Jun 2021 15:38:18

	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)		30 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		30 AUG 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 20 Apr 2021 13:55:48

Generated On: 09 Jun 2021 15:38:18

Name of Medication CHEMOTHERAPY

Prophylaxis Yes ☐
No ☒

Indication PANCREATIC CANCER

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNKNOWN

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 UNKNOWN

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) 20 Apr 2021 13:55:48

Generated On: 09 Jun 2021 15:38:18

	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 checked="" type="radio"/>
If route of administration is Other, specify	UNKNOWN	
Start date (dd MMM yyyy)	17 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 20 Apr 2021 13:55:48

Generated On: 09 Jun 2021 15:38:18

Name of Medication	RADIESSE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	COSMETIC FACIAL FILLER
Dose per administration	UNKNOWN
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input checked="" type="radio"/>
If dose unit is Other, specify	UNKNOWN
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input checked="" type="radio"/>
If frequency is Other, specify	EVERY 12-14 MONTHS
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/>

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 20 Apr 2021 13:55:48

Generated On: 09 Jun 2021 15:38:18

	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 checked="" type="radio"/>
If route of administration is Other, specify	PERCUTANEOUS	
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	UN JUN 2020	
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 20 Apr 2021 13:55:48

Generated On: 09 Jun 2021 15:38:18

Name of Medication JUVEDERM

Prophylaxis Yes ☐
No ☒

Indication COSMETIC FACIAL FILLER

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify EVERY 12-14 MONTHS

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) 20 Apr 2021 13:55:48

Generated On: 09 Jun 2021 15:38:18

	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 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		UN JUN 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 20 Apr 2021 13:55:48

Generated On: 09 Jun 2021 15:38:18

Name of Medication BOTOX

Prophylaxis Yes ☐
No ☒

Indication COSMETIC FACIAL FILLER

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify EVERY 12-14 MONTHS

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 20 Apr 2021 13:55:48

Generated On: 09 Jun 2021 15:38:18

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		UN JUN 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3182065

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 09 Mar 2021 04:06:44

Generated On: 09 Jun 2021 15:38:18

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3182065

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:38:18

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 ☐

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Data signed: (b) (4) 23 Apr 2021 15:17:48

Generated On: 09 Jun 2021 15:38:18

SAEID	USA-US075-2021-MRNA-1273-P301000006
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	TOBY
Investigator's Last Name	BRISKIN
Site Address: Street	3619 PARK EAST DRIVE, SUITE 300
Site Address: City	BEACHWOOD
Site Address: State	OH
Site Address: Postal Code	44122
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Data signed: (b) (4) 23 Apr 2021 15:17:48

Generated On: 09 Jun 2021 15:38:18

SAEID	USA-US075-2021-MRNA-1273-P301000006
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	TOBY
Investigator's Last Name	BRISKIN
Site Address: Street	3619 PARK EAST DRIVE, SUITE 300
Site Address: City	BEACHWOOD
Site Address: State	OH
Site Address: Postal Code	44122
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	17/FEB/2021 10:44
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form (2)

Data signed: (b) (4) 23 Apr 2021 15:17:48

Generated On: 09 Jun 2021 15:38:18

SAEID	USA-US075-2021-MRNA-1273-P301000006
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	TOBY
Investigator's Last Name	BRISKIN
Site Address: Street	3619 PARK EAST DRIVE, SUITE 300
Site Address: City	BEACHWOOD
Site Address: State	OH
Site Address: Postal Code	44122
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	26/MAR/2021 19:19
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form (3)

Data signed: (b) (4) 23 Apr 2021 15:17:48

Generated On: 09 Jun 2021 15:38:18

SAEID	USA-US075-2021-MRNA-1273-P301000006
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	TOBY
Investigator's Last Name	BRISKIN
Site Address: Street	3619 PARK EAST DRIVE, SUITE 300
Site Address: City	BEACHWOOD
Site Address: State	OH
Site Address: Postal Code	44122
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	12/APR/2021 15:21
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form (4)

Data signed: (b) (4) 23 Apr 2021 15:17:48

Generated On: 09 Jun 2021 15:38:18

SAEID	USA-US075-2021-MRNA-1273-P301000006
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	TOBY
Investigator's Last Name	BRISKIN
Site Address: Street	3619 PARK EAST DRIVE, SUITE 300
Site Address: City	BEACHWOOD
Site Address: State	OH
Site Address: Postal Code	44122
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	14/APR/2021 12:27
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form (5)

Data signed: (b) (4) 23 Apr 2021 15:17:48

Generated On: 09 Jun 2021 15:38:18

SAEID	USA-US075-2021-MRNA-1273-P301000006
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 type="radio"/> No <input checked="" 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 checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	TOBY
Investigator's Last Name	BRISKIN
Site Address: Street	3619 PARK EAST DRIVE, SUITE 300
Site Address: City	BEACHWOOD
Site Address: State	OH
Site Address: Postal Code	44122
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	23/APR/2021 09:26
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.	True

Audit

US3182065 (Prod: Rapid Medical Research Inc - ERN-PPDS)

US3182065

Form: Participant Creation

Generated On: 09 Jun 2021 15:38:18

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:06:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Aug 2020 21:09:18
User entered 'US3182065'	RWS_ENDPOINT ENDPOINT (b) (4)	29 Jul 2020 19:34:16

US3182065

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:38:18

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:35:33
User entered 'Yes (Y)'	Brooke Glivar (b) (4) (b) (4)	31 Jul 2020 21:25:02

US3182065

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:38:53
User entered '29 JUL 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	29 Jul 2020 19:34:17

US3182065

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:38:57
User entered 'Clinic (Clinic)'	Brooke Glivar (b) (4) (b) (4)	31 Jul 2020 21:25:02

US3182065

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:38:18

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User entered 'SCRN'	System	31 Jul 2020 21:25:02

US3182065

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:38:18

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:39:24
User entered (b) (6) 1960'	RWS_ENDPOINT ENDPOINT (b) (4)	29 Jul 2020 19:34:18

US3182065

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:38:18

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:39:25
User entered '60'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:01:42

US3182065

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:38:18

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User entered 'YEARS'	System	04 Aug 2020 14:01:42

US3182065

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:38:18

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User entered '60'	System	29 Jul 2020 21:37:34

US3182065

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:38:18

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:39:51
User entered 'Female (F)'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:01:42

US3182065

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:38:18

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:39:56
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:01:42

US3182065

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:38:18

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:39:59
User entered 'I'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:01:42

US3182065

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:38:18

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:40:02
User entered '0'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:01:42

US3182065

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:38:18

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:40:02
User entered '0'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:01:42

US3182065

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:38:18

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:40:02
User entered '0'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:01:42

US3182065

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:38:18

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:40:02
User entered '0'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:01:42

US3182065

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:38:18

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:40:02
User entered '0'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:01:42

US3182065

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:38:18

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:40:02
User entered empty.	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:01:42

US3182065

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:38:18

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:40:02
User entered '0'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:01:42

US3182065

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:38:18

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:40:02
User entered '0'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:01:42

US3182065

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:38:18

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:40:07
User entered '29 Jul 2020'	Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 21:37:34

US3182065

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User entered 'Jul 2020'	System	29 Jul 2020 21:37:34

US3182065

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User entered '2020'	System	29 Jul 2020 21:37:34

US3182065

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:38:18

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:40:12
User entered 'Amendment 1 (1)'	Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 21:37:34

US3182065

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:40:12
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 21:37:34

US3182065

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:38:18

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:40:12
User entered empty.	Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 21:37:34

US3182065

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:38:18

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:40:12
User entered empty.	Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 21:37:34

US3182065

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:38:18

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:40:12
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 21:37:34

US3182065

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:38:18

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:40:12
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	29 Jul 2020 19:34:17

US3182065

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:38:18

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User entered 'I'	System	29 Jul 2020 21:37:34

US3182065

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:48:46
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	29 Jul 2020 21:36:29

US3182065

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:38:18

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:42:06
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:08:32

US3182065

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:38:18

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:42:22
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.	Coder Import (b) (4) (b) (4)	04 Aug 2020 14:09:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 14:09:02
Data point term sent to Coder	System	04 Aug 2020 14:08:49
User entered 'Seasonal Allergies'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:08:46

US3182065

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:42:22
User entered 'un UNK 1974'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:08:46

US3182065

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:38:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:42:22
User entered '0'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:08:46

US3182065

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:38:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:42:22
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:08:46

US3182065

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:42:22
User entered empty.	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:08:46

US3182065

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:38:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:42:22
User entered '0'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:08:46

US3182065

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:38:18

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User entered 'Jan 1974'	System	04 Aug 2020 14:08:46

US3182065

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:38:18

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User entered '1974'	System	04 Aug 2020 14:08:46

US3182065

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User entered empty.	System	04 Aug 2020 14:08:46

US3182065

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User entered empty.	System	04 Aug 2020 14:08:46

US3182065

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:38:18

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:42:34
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Tonsillar therapeutic procedures, PT: Tonsillectomy, LLT: Tonsillectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 14:12:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 14:12:00
Data point term sent to Coder	System	04 Aug 2020 14:10:52
User entered 'Tonsillectomy'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:09:56

US3182065

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:42:34
User entered 'un UNK 1966'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:09:56

US3182065

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:38:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:42:34
User entered '0'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:09:56

US3182065

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:38:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:42:34
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:09:56

US3182065

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:42:34
User entered 'un UNK 1966'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:09:56

US3182065

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:38:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:42:34
User entered '0'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:09:56

US3182065

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User entered 'Jan 1966'	System	04 Aug 2020 14:09:56

US3182065

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:38:18

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User entered '1966'	System	04 Aug 2020 14:09:56

US3182065

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User entered 'Jan 1966'	System	04 Aug 2020 14:09:56

US3182065

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User entered '1966'	System	04 Aug 2020 14:09:56

US3182065

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:38:18

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 18:08:43
User closed query 'Per DM CLR: Please update the condition to include the laterality of Myopia (e.g. Left, Right or Bilateral). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).		29 Sep 2020 02:18:22
User coded data point as SOC: Eye disorders, HLGT: Coders Import Vision disorders, HLT: Refractive and accommodative disorders, PT: Myopia, LLT: Myopia - version MedDRA\23.0.	(b) (4) (b) (4)	25 Sep 2020 17:07:49
User coded data point as Term Coded data point by User: Coders System - version MedDRA\23.0.	Coders Import (b) (4) (b) (4)	25 Sep 2020 17:07:49
Data point term sent to Coders System	System	25 Sep 2020 16:47:14
Query 'Per DM CLR: Please update the condition to include the laterality of Myopia (e.g. Left, Right or Bilateral). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'Updated' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	25 Sep 2020 16:46:48
DataPoint Un-verified.	Cassie Uminski (b) (4) (b) (4)	25 Sep 2020 16:46:45
Coding entries removed.	Cassie Uminski (b) (4) (b) (4)	25 Sep 2020 16:46:45
User entered 'Bilateral MYOPIA' reason for change: Data Entry Error	Cassie Uminski (b) (4) (b) (4)	25 Sep 2020 16:46:45
User opened query 'Per DM CLR: Please update the condition to include the laterality of Myopia (e.g. Left, Right or Bilateral). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 03:40:41
DataPoint Verified.	(b) (4), (b) (6)	18 Aug 2020 18:42:40

US3182065

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:38:18

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Myopia, LLT: Myopia - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 18:17:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 18:17:55
Data point term sent to Coder	System	06 Aug 2020 17:57:45
User entered 'Myopia'	Cassie Uminski (b) (4)	06 Aug 2020 17:57:39
	(b) (4)	

US3182065

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:42:40
User entered 'un UNK 1973'	Cassie Uminski (b) (4) (b) (4)	06 Aug 2020 17:57:39

US3182065

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:38:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:42:40
User entered '0'	Cassie Uminski (b) (4) (b) (4)	06 Aug 2020 17:57:39

US3182065

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:38:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:42:40
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	06 Aug 2020 17:57:39

US3182065

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:42:40
User entered empty.	Cassie Uminski (b) (4) (b) (4)	06 Aug 2020 17:57:39

US3182065

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:38:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:42:40
User entered '0'	Cassie Uminski (b) (4) (b) (4)	06 Aug 2020 17:57:39

US3182065

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:38:18

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User entered 'Jan 1973'	System	06 Aug 2020 17:57:39

US3182065

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User entered '1973'	System	06 Aug 2020 17:57:39

US3182065

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User entered empty.	System	06 Aug 2020 17:57:39

US3182065

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User entered empty.	System	06 Aug 2020 17:57:39

US3182065

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:38:18

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:43:07
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Tonsillitis, LLT: Tonsillitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Aug 2020 18:17:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Aug 2020 18:17:57
Data point term sent to Coder	System	06 Aug 2020 17:58:46
User entered 'Tonsillitis'	Cassie Uminski (b) (4) (b) (4)	06 Aug 2020 17:58:07

US3182065

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:43:07
User entered 'un UNK 1966'	Cassie Uminski (b) (4) (b) (4)	06 Aug 2020 17:58:07

US3182065

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:38:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:43:07
User entered '0'	Cassie Uminski (b) (4) (b) (4)	06 Aug 2020 17:58:07

US3182065

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:38:18

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:43:07
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	06 Aug 2020 17:58:07

US3182065

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:43:07
User entered 'un UNK 1966'	Cassie Uminski (b) (4) (b) (4)	06 Aug 2020 17:58:07

US3182065

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:38:18

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:43:07
User entered '0'	Cassie Uminski (b) (4) (b) (4)	06 Aug 2020 17:58:07

US3182065

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:38:18

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User entered 'Jan 1966'	System	06 Aug 2020 17:58:07

US3182065

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:38:18

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User entered '1966'	System	06 Aug 2020 17:58:07

US3182065

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User entered 'Jan 1966'	System	06 Aug 2020 17:58:07

US3182065

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User entered '1966'	System	06 Aug 2020 17:58:07

US3182065

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:44:21
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:02:42

US3182065

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:44:21
User entered '29 Jul 2020'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:02:42

US3182065

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:44:21
User entered '15:33'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:02:42

US3182065

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User entered '29 Jul 2020 15:33'	System	04 Aug 2020 14:02:42

US3182065

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:18

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:44:21
User entered '166.0' cm	Cassie Uminski (b) (4)	04 Aug 2020 14:02:42
DataPoint set to visible.	(b) (4) System	29 Jul 2020 21:37:34

US3182065

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:44:21
User entered '66.2' kg	Cassie Uminski (b) (4)	04 Aug 2020 14:02:42
DataPoint set to visible.	(b) (4) System	29 Jul 2020 21:37:34

US3182065

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:18

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
Amendment Manager: User entered '24.02381'	System	16 Sep 2020 23:38:23
User entered '24.0'	System	04 Aug 2020 14:02:42
DataPoint set to visible.	System	29 Jul 2020 21:37:34

US3182065

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:18

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User entered 'kg/m2'	System	04 Aug 2020 14:02:42
DataPoint set to visible.	System	29 Jul 2020 21:37:34

US3182065

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:44:21
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:02:42

US3182065

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 18:13:24
User closed query 'Per CDM: Since Temperature is ND, please consider to remove data recorded here. ' (Site from DM).		29 Sep 2020 02:54:14
DataPoint Un-verified.	Cassie Uminski (b) (4)	24 Sep 2020 18:46:39
User entered empty; reason for change Data Entry Error	(b) (4) Cassie Uminski (b) (4)	24 Sep 2020 18:46:39
Query 'Per CDM: Since Temperature is ND, please consider to remove data recorded here. ' answered with 'Updated' (Site from DM).	(b) (4) Cassie Uminski (b) (4)	24 Sep 2020 18:46:32
User opened query 'Per CDM: Since Temperature is ND, please consider to remove data recorded here. ' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 01:50:18
DataPoint Verified.		18 Aug 2020 18:44:21
User entered 'Other (Other)'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:02:42

US3182065

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 18:13:25
DataPoint Un-verified.	Cassie Uminski (b) (4)	24 Sep 2020 18:46:39
User entered empty; reason for change Data Entry Error	(b) (4) Cassie Uminski (b) (4)	24 Sep 2020 18:46:39
DataPoint Verified.	(b) (4), (b) (6)	18 Aug 2020 18:44:21
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:02:42

US3182065

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:44:21
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:02:42

US3182065

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User entered 'bpm'	System	04 Aug 2020 14:02:42

US3182065

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:44:21
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:02:42

US3182065

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User entered 'breaths/min'	System	04 Aug 2020 14:02:42

US3182065

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:44:21
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:02:42

US3182065

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User entered 'mmHg'	System	04 Aug 2020 14:02:42

US3182065

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:44:21
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:02:42

US3182065

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:18

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User entered 'mmHg'	System	04 Aug 2020 14:02:42

US3182065

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:18

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01

US3182065

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:18

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01

US3182065

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:38:18

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:44:35
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:06:17

US3182065

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:38:18

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	07 Sep 2020 08:39:32
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	31 Aug 2020 18:26:19
DataPoint Verified.	(b) (4), (b) (6)	18 Aug 2020 18:44:36
User entered '29 Jul 2020'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:06:17

US3182065

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:38:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:45:17
User entered '29 Jul 2020'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:05:13

US3182065

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:45:17
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:05:13

US3182065

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:45:17
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:05:13

US3182065

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:38:18

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:45:17
User entered empty.	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:05:13

US3182065

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:45:17
User entered empty.	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:05:13

US3182065

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:38:18

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:45:17
User entered '0'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:05:13

US3182065

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:45:17
User entered 'un UNK 2009'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:05:13

US3182065

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:38:18

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:45:17
User entered '0'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:05:13

US3182065

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:47:56
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:08:22

US3182065

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:47:56
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:08:22

US3182065

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:47:56
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:08:22

US3182065

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:47:56
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:08:22

US3182065

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:47:56
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:08:22

US3182065

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:47:56
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:08:22

US3182065

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:47:56
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:08:22

US3182065

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:47:56
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:08:22

US3182065

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:47:56
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:08:22

US3182065

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:47:56
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:08:22

US3182065

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:47:56
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:08:22

US3182065

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:38:18

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:47:56
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:08:22

US3182065

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:38:18

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:47:56
User entered empty.	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:08:22

US3182065

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:38:18

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
User entered 'I'	Cassie Uminski	04 Aug 2020 14:08:22

US3182065

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:47:56
User entered '0'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:08:22

US3182065

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:47:56
User entered '0'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:08:22

US3182065

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:47:56
User entered '0'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:08:22

US3182065

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:47:56
User entered '0'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:08:22

US3182065

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:47:56
User entered '0'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:08:22

US3182065

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:38:18

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
User entered '0'	Cassie Uminski	04 Aug 2020 14:08:22

US3182065

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:38:18

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:05:01
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:34:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:47:56
User entered empty.	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:08:22

US3182065

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:38:18

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:49:11
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:07:52

US3182065

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:49:11
User entered '29 Jul 2020'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:07:52

US3182065

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:49:11
User entered 'Clinic (Clinic)'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:07:52

US3182065

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:38:18

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User entered 'VISIT1'	System	04 Aug 2020 14:07:52

US3182065

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:49:17
User entered '29 JUL 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	29 Jul 2020 20:14:19

US3182065

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 01:49:21
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 01:17:21
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:17:21
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	29 Jul 2020 20:14:19
User entered '142290' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	29 Jul 2020 20:14:19

US3182065

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
User closed query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	07 Oct 2020 18:44:01
User closed query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from DM).		07 Oct 2020 18:44:00
Query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' answered with 'this was an entry error in IWRS' (Site from System).	Amy Maroun (b) (4) (b) (4)	03 Oct 2020 20:45:24
Amendment Manager: User opened query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from System).	System	30 Sep 2020 21:08:05
Query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' answered with 'Unable to update in endpoint, subject not at risk' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	30 Sep 2020 18:46:43
User opened query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 17:38:09
Query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' canceled (Site from System).		30 Sep 2020 17:38:01
DataPoint Verified.		18 Aug 2020 18:56:37
User opened query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from System).	System	04 Aug 2020 14:05:38
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	29 Jul 2020 20:14:19

US3182065

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:56:47
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:05:38

US3182065

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:56:49
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:05:38

US3182065

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:56:50
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:05:38

US3182065

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:38:18

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:56:53
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:05:38

US3182065

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:38:18

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:56:52
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:05:38

US3182065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:38:18

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:57:26
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:03:53

US3182065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:38:18

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:57:28
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:03:53

US3182065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:38:18

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:57:26
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:03:53

US3182065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:38:18

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:57:28
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:03:53

US3182065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:18

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User accepted default value 'Pre-Dose (PREDOSE)'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:03:53

US3182065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:59:05
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:03:53

US3182065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:59:05
User entered '29 Jul 2020'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:03:53

US3182065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:59:05
User entered '15:33'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:03:53

US3182065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User entered '29 Jul 2020 15:33'	System	04 Aug 2020 14:03:53

US3182065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:59:05
User entered '98.2' F	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:03:53

US3182065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:59:05
User entered 'Oral (Oral)'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:03:53

US3182065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:59:05
User entered empty.	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:03:53

US3182065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:59:05
User entered '77'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:03:53

US3182065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User entered 'bpm'	System	04 Aug 2020 14:03:53

US3182065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:59:05
User entered '16'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:03:53

US3182065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User entered 'breaths/min'	System	04 Aug 2020 14:03:53

US3182065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:59:05
User entered '124'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:03:53

US3182065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User entered 'mmHg'	System	04 Aug 2020 14:03:53

US3182065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:59:05
User entered '80'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:03:53

US3182065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:18

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User entered 'mmHg'	System	04 Aug 2020 14:03:53

US3182065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:38:18

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:57:26
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:03:53

US3182065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:38:18

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:57:28
User entered missing code ND - Not Done.	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:03:53

US3182065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:18

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User accepted default value 'Post-Dose (POSTDOSE)'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:03:53

US3182065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:59:05
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:03:53

US3182065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:59:05
User entered '29 Jul 2020'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:03:53

US3182065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:59:05
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).		17 Aug 2020 18:38:33
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		04 Aug 2020 14:03:53
User entered '17:02'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:03:53

US3182065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User entered '29 Jul 2020 17:02'	System	04 Aug 2020 14:03:53

US3182065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:59:05
User entered '98.5' F	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:03:53

US3182065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:59:05
User entered 'Oral (Oral)'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:03:53

US3182065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:59:05
User entered empty.	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:03:53

US3182065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:59:05
User entered '74'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:03:53

US3182065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User entered 'bpm'	System	04 Aug 2020 14:03:53

US3182065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:59:05
User entered '16'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:03:53

US3182065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User entered 'breaths/min'	System	04 Aug 2020 14:03:53

US3182065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:59:05
User entered '114'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:03:53

US3182065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User entered 'mmHg'	System	04 Aug 2020 14:03:53

US3182065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 18:59:05
User entered '77'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:03:53

US3182065

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:18

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User entered 'mmHg'	System	04 Aug 2020 14:03:53

US3182065

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:38:18

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 19:01:37
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:06:21

US3182065

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:38:18

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 19:01:37
User entered empty.	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:06:21

US3182065

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:38:18

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 19:02:33
User entered 'Yes (Y)'	Brooke Glivar (b) (4) (b) (4)	31 Jul 2020 21:28:45

US3182065

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:38:18

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 19:02:33
User entered empty.	Brooke Glivar (b) (4) (b) (4)	31 Jul 2020 21:28:45

US3182065

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)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 19:02:33
User entered empty.	Brooke Glivar (b) (4) (b) (4)	31 Jul 2020 21:28:45

US3182065

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:38:18

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User entered 'MRNA-1273 OR PLACEBO'	System	31 Jul 2020 21:28:45

US3182065

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:38:18

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 19:02:33
User entered '29 Jul 2020'	Brooke Glivar (b) (4) (b) (4)	31 Jul 2020 21:28:45

US3182065

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 19:02:33
User entered '16:27'	Brooke Glivar (b) (4) (b) (4)	31 Jul 2020 21:28:45

US3182065

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User entered '29 Jul 2020 16:27'	System	31 Jul 2020 21:28:45

US3182065

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 19:02:33
User entered 'Left Arm (LEFT ARM)'	Brooke Glivar (b) (4) (b) (4)	31 Jul 2020 21:28:45

US3182065

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:38:18

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
DataPoint Verified.		18 Aug 2020 19:02:33
User entered 'ONCE'	System	31 Jul 2020 21:28:45

US3182065

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:38:18

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User entered 'INTRAMUSCULAR'	System	31 Jul 2020 21:28:45

US3182065

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:38:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 19:02:47
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:07:38

US3182065

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:38:18

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 19:02:49
User entered '29 Jul 2020'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:07:38

US3182065

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:38:18

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 19:02:49
User entered '15:35'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:07:38

US3182065

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User entered '29 Jul 2020 15:35'	System	04 Aug 2020 14:07:38

US3182065

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:38:18

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 19:02:55
User entered '29 Jul 2020'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:06:32

US3182065

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:38:18

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Cassie Uminski (b) (4)	04 Aug 2020 14:06:32
	(b) (4)	

US3182065

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:38:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 19:02:59
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:06:32

US3182065

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:38:18

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 19:02:59
User entered '15:50'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:06:32

US3182065

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:38:18

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User entered '29 Jul 2020 15:50'	System	04 Aug 2020 14:06:32

US3182065

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:38:18

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Cassie Uminski (b) (4)	04 Aug 2020 14:06:32
	(b) (4)	

US3182065

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:38:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 19:03:02
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:06:32

US3182065

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:38:18

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 19:03:02
User entered empty.	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:06:32

US3182065

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:38:18

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User entered empty.	System	04 Aug 2020 14:06:32

US3182065

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 19:03:07
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:07:43

US3182065

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:38:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User entered 'I'	System	04 Aug 2020 14:07:43

US3182065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
Data entry locked.	System	31 Jul 2020 21:28:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Jul 2020 21:28:45

US3182065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:38:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38

US3182065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:38:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38

US3182065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38

US3182065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38

US3182065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:38:18

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38

US3182065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:38:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38

US3182065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:38:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '29 Jul 2020 16:47'	System	31 Jul 2020 21:28:45

US3182065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:38:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '29 Jul 2020 19:17'	System	31 Jul 2020 21:28:45

US3182065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
Data entry locked.	System	31 Jul 2020 21:28:45
User entered 'Day 1, after vaccination (at home)'	System	31 Jul 2020 21:28:45

US3182065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:38:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38

US3182065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:38:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38

US3182065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38

US3182065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38

US3182065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:38:18

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38

US3182065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:38:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38

US3182065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:38:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '29 Jul 2020 20:12'	System	31 Jul 2020 21:28:45

US3182065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:38:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '30 Jul 2020 11:59'	System	31 Jul 2020 21:28:45

US3182065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
Data entry locked.	System	31 Jul 2020 21:28:45
User entered 'Day 2'	System	31 Jul 2020 21:28:45

US3182065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:38:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38

US3182065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:38:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38

US3182065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38

US3182065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38

US3182065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:38:18

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38

US3182065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:38:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38

US3182065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:38:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '30 Jul 2020 12:00'	System	31 Jul 2020 21:28:45

US3182065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:38:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '31 Jul 2020 11:59'	System	31 Jul 2020 21:28:45

US3182065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
Data entry locked.	System	31 Jul 2020 21:28:45
User entered 'Day 3'	System	31 Jul 2020 21:28:45

US3182065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:38:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-07-31T18:30:57', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '08dfa4a1-3b88-4e3d-b8d0-f65b5cbc3f6f' User entered 'Yes (Y)'	System	31 Jul 2020 22:31:45
	System	31 Jul 2020 22:31:45

US3182065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:38:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-07-31T18:31:27', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '08dfa4a1-3b88-4e3d-b8d0-f65b5cbc3f6f' User entered '97.1'	System	31 Jul 2020 22:31:45
	System	31 Jul 2020 22:31:45

US3182065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-07-31T18:31:31', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '08dfa4a1-3b88-4e3d-b8d0-f65b5cbc3f6f' User entered 'No (N)'	System	31 Jul 2020 22:31:45
	System	31 Jul 2020 22:31:45

US3182065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:38:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-07-31T18:31:41', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '08dfa4a1-3b88-4e3d-b8d0-f65b5cbc3f6f' User entered '31 Jul 2020 18:31'	System	31 Jul 2020 22:31:45
	System	31 Jul 2020 22:31:45

US3182065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:38:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '31 Jul 2020 12:00'	System	31 Jul 2020 21:28:45

US3182065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:38:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '01 Aug 2020 11:59'	System	31 Jul 2020 21:28:45

US3182065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
Data entry locked.	System	31 Jul 2020 21:28:45
User entered 'Day 4'	System	31 Jul 2020 21:28:45

US3182065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:38:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-01T19:22:39', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'a53f76d3-93da-4fc8-9adc-0d41d7005488' User entered 'Yes (Y)'	System	01 Aug 2020 23:23:04
	System	01 Aug 2020 23:23:04

US3182065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:38:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-01T19:22:49', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'a53f76d3-93da-4fc8-9adc-0d41d7005488' User entered '96.1'	System	01 Aug 2020 23:23:04
	System	01 Aug 2020 23:23:04

US3182065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-01T19:22:53', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'a53f76d3-93da-4fc8-9adc-0d41d7005488' User entered 'No (N)'	System	01 Aug 2020 23:23:04
	System	01 Aug 2020 23:23:04

US3182065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:38:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-01T19:22:59', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'a53f76d3-93da-4fc8-9adc-0d41d7005488' User entered '01 Aug 2020 19:22'	System	01 Aug 2020 23:23:04
	System	01 Aug 2020 23:23:04

US3182065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:38:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '01 Aug 2020 12:00'	System	31 Jul 2020 21:28:45

US3182065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:38:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '02 Aug 2020 11:59'	System	31 Jul 2020 21:28:45

US3182065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
Data entry locked.	System	31 Jul 2020 21:28:45
User entered 'Day 5'	System	31 Jul 2020 21:28:45

US3182065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:38:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-02T13:06:29', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '68e3500c-fbc6-42b1-9000-90b5f953fd78' User entered 'Yes (Y)'	System	02 Aug 2020 17:07:07
	System	02 Aug 2020 17:07:07

US3182065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:38:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-02T13:06:55', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '68e3500c-fbc6-42b1-9000-90b5f953fd78' User entered '96.8'	System	02 Aug 2020 17:07:07
	System	02 Aug 2020 17:07:07

US3182065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-02T13:06:59', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '68e3500c-fbc6-42b1-9000-90b5f953fd78' User entered 'No (N)'	System	02 Aug 2020 17:07:07
	System	02 Aug 2020 17:07:07

US3182065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:38:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-02T13:07:03', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '68e3500c-fbc6-42b1-9000-90b5f953fd78' User entered '02 Aug 2020 13:07'	System	02 Aug 2020 17:07:07
	System	02 Aug 2020 17:07:07

US3182065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:38:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '02 Aug 2020 12:00'	System	31 Jul 2020 21:28:45

US3182065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:38:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '03 Aug 2020 11:59'	System	31 Jul 2020 21:28:45

US3182065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
Data entry locked.	System	31 Jul 2020 21:28:45
User entered 'Day 6'	System	31 Jul 2020 21:28:45

US3182065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:38:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-03T18:20:32', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'fdcc6063-8f4b-484b-91b4-d4c988c3119a' User entered 'Yes (Y)'	System	03 Aug 2020 22:20:53
	System	03 Aug 2020 22:20:53

US3182065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:38:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-03T18:20:42', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'fdcc6063-8f4b-484b-91b4-d4c988c3119a' User entered '96.8'	System	03 Aug 2020 22:20:53
	System	03 Aug 2020 22:20:53

US3182065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-03T18:20:46', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'fdcc6063-8f4b-484b-91b4-d4c988c3119a' User entered 'No (N)'	System	03 Aug 2020 22:20:53
	System	03 Aug 2020 22:20:53

US3182065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:38:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-03T18:20:50', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'fdcc6063-8f4b-484b-91b4-d4c988c3119a'	System	03 Aug 2020 22:20:53
User entered '03 Aug 2020 18:20'	System	03 Aug 2020 22:20:53

US3182065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:38:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '03 Aug 2020 12:00'	System	31 Jul 2020 21:28:45

US3182065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:38:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '04 Aug 2020 11:59'	System	31 Jul 2020 21:28:45

US3182065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
Data entry locked.	System	31 Jul 2020 21:28:45
User entered 'Day 7'	System	31 Jul 2020 21:28:45

US3182065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:38:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-04T23:56:27', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '1caab012-e66c-4ed2-88f9-726b931121d7' User entered 'Yes (Y)'	System	05 Aug 2020 03:56:42
	System	05 Aug 2020 03:56:42

US3182065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:38:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-04T23:56:34', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '1caab012-e66c-4ed2-88f9-726b931121d7' User entered '96.8'	System	05 Aug 2020 03:56:42
	System	05 Aug 2020 03:56:42

US3182065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-04T23:56:37', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '1caab012-e66c-4ed2-88f9-726b931121d7'	System	05 Aug 2020 03:56:42
User entered 'No (N)'	System	05 Aug 2020 03:56:42

US3182065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:38:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-04T23:56:40', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '1caab012-e66c-4ed2-88f9-726b931121d7'	System	05 Aug 2020 03:56:42
User entered '04 Aug 2020 23:56'	System	05 Aug 2020 03:56:42

US3182065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:38:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '04 Aug 2020 12:00'	System	31 Jul 2020 21:28:45

US3182065

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:38:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '05 Aug 2020 11:59'	System	31 Jul 2020 21:28:45

US3182065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
Data entry locked.	System	31 Jul 2020 21:28:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Jul 2020 21:28:45

US3182065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:38:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38

US3182065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:38:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38

US3182065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:38:18

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38

US3182065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:38:18

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38

US3182065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:38:18

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38

US3182065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:38:18

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38

US3182065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:38:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38

US3182065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:38:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '29 Jul 2020 16:47'	System	31 Jul 2020 21:28:45

US3182065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:38:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '29 Jul 2020 19:17'	System	31 Jul 2020 21:28:45

US3182065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
Data entry locked.	System	31 Jul 2020 21:28:45
User entered 'Day 1, after vaccination (at home)'	System	31 Jul 2020 21:28:45

US3182065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:38:18

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38

US3182065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:38:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38

US3182065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:38:18

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38

US3182065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:38:18

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38

US3182065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:38:18

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38

US3182065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:38:18

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38

US3182065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:38:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38

US3182065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:38:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '29 Jul 2020 20:12'	System	31 Jul 2020 21:28:45

US3182065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:38:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '30 Jul 2020 11:59'	System	31 Jul 2020 21:28:45

US3182065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
Data entry locked.	System	31 Jul 2020 21:28:45
User entered 'Day 2'	System	31 Jul 2020 21:28:45

US3182065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:38:18

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38

US3182065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:38:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38

US3182065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:38:18

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38

US3182065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:38:18

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38

US3182065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:38:18

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38

US3182065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:38:18

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38

US3182065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:38:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38

US3182065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:38:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '30 Jul 2020 12:00'	System	31 Jul 2020 21:28:45

US3182065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:38:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '31 Jul 2020 11:59'	System	31 Jul 2020 21:28:45

US3182065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
Data entry locked.	System	31 Jul 2020 21:28:45
User entered 'Day 3'	System	31 Jul 2020 21:28:45

US3182065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:38:18

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-07-31T18:31:49', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '0394eaab-850d-4e88-af59-7a426b14c705'	System	31 Jul 2020 22:32:11
User entered 'None (1)'	System	31 Jul 2020 22:32:11

US3182065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:38:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-07-31T18:31:53', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '0394eaab-850d-4e88-af59-7a426b14c705' User entered 'No (N)'	System	31 Jul 2020 22:32:11
	System	31 Jul 2020 22:32:11

US3182065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:38:18

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-07-31T18:31:55', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '0394eaab-850d-4e88-af59-7a426b14c705' User entered 'No (N)'	System	31 Jul 2020 22:32:11
	System	31 Jul 2020 22:32:11

US3182065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:38:18

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-07-31T18:32:00', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '0394eaab-850d-4e88-af59-7a426b14c705'	System	31 Jul 2020 22:32:11
User entered 'None (1)'	System	31 Jul 2020 22:32:11

US3182065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:38:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-07-31T18:32:08', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '0394eaab-850d-4e88-af59-7a426b14c705' User entered '31 Jul 2020 18:32'	System	31 Jul 2020 22:32:11
	System	31 Jul 2020 22:32:11

US3182065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:38:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '31 Jul 2020 12:00'	System	31 Jul 2020 21:28:45

US3182065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:38:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '01 Aug 2020 11:59'	System	31 Jul 2020 21:28:45

US3182065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
Data entry locked.	System	31 Jul 2020 21:28:45
User entered 'Day 4'	System	31 Jul 2020 21:28:45

US3182065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:38:18

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-01T19:23:05', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'fd79e887-62a0-4b34-ae14-bb80d35884fc' User entered 'None (1)'	System	01 Aug 2020 23:23:22
	System	01 Aug 2020 23:23:22

US3182065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:38:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-01T19:23:09', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'fd79e887-62a0-4b34-ae14-bb80d35884fc' User entered 'No (N)'	System	01 Aug 2020 23:23:22
	System	01 Aug 2020 23:23:22

US3182065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:38:18

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-01T19:23:12', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'fd79e887-62a0-4b34-ae14-bb80d35884fc' User entered 'No (N)'	System	01 Aug 2020 23:23:22
	System	01 Aug 2020 23:23:22

US3182065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:38:18

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-01T19:23:16', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'fd79e887-62a0-4b34-ae14-bb80d35884fc' User entered 'None (1)'	System	01 Aug 2020 23:23:22
	System	01 Aug 2020 23:23:22

US3182065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:38:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-01T19:23:20', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'fd79e887-62a0-4b34-ae14-bb80d35884fc' User entered '01 Aug 2020 19:23'	System	01 Aug 2020 23:23:22
	System	01 Aug 2020 23:23:22

US3182065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:38:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '01 Aug 2020 12:00'	System	31 Jul 2020 21:28:45

US3182065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:38:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '02 Aug 2020 11:59'	System	31 Jul 2020 21:28:45

US3182065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
Data entry locked.	System	31 Jul 2020 21:28:45
User entered 'Day 5'	System	31 Jul 2020 21:28:45

US3182065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:38:18

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-02T13:07:09', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'a0d2d4c6-3efa-433e-82a8-b33dca41a616' User entered 'None (1)'	System	02 Aug 2020 17:07:28
	System	02 Aug 2020 17:07:28

US3182065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:38:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-02T13:07:12', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'a0d2d4c6-3efa-433e-82a8-b33dca41a616' User entered 'No (N)'	System	02 Aug 2020 17:07:28
	System	02 Aug 2020 17:07:28

US3182065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:38:18

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-02T13:07:14', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'a0d2d4c6-3efa-433e-82a8-b33dca41a616' User entered 'No (N)'	System	02 Aug 2020 17:07:28
	System	02 Aug 2020 17:07:28

US3182065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:38:18

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-02T13:07:18', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'a0d2d4c6-3efa-433e-82a8-b33dca41a616' User entered 'None (1)'	System	02 Aug 2020 17:07:28
	System	02 Aug 2020 17:07:28

US3182065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:38:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-02T13:07:25', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'a0d2d4c6-3efa-433e-82a8-b33dca41a616' User entered '02 Aug 2020 13:07'	System	02 Aug 2020 17:07:28
	System	02 Aug 2020 17:07:28

US3182065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:38:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '02 Aug 2020 12:00'	System	31 Jul 2020 21:28:45

US3182065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:38:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '03 Aug 2020 11:59'	System	31 Jul 2020 21:28:45

US3182065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
Data entry locked.	System	31 Jul 2020 21:28:45
User entered 'Day 6'	System	31 Jul 2020 21:28:45

US3182065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:38:18

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-03T18:20:57', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'a8a6668f-150e-406b-8eb6-8eb5cc05fa13'	System	03 Aug 2020 22:21:17
User entered 'None (1)'	System	03 Aug 2020 22:21:17

US3182065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:38:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-03T18:21:00', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'a8a6668f-150e-406b-8eb6-8eb5cc05fa13'	System	03 Aug 2020 22:21:17
User entered 'No (N)'	System	03 Aug 2020 22:21:17

US3182065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:38:18

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-03T18:21:03', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'a8a6668f-150e-406b-8eb6-8eb5cc05fa13'	System	03 Aug 2020 22:21:17
User entered 'No (N)'	System	03 Aug 2020 22:21:17

US3182065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:38:18

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-03T18:21:07', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'a8a6668f-150e-406b-8eb6-8eb5cc05fa13'	System	03 Aug 2020 22:21:17
User entered 'None (1)'	System	03 Aug 2020 22:21:17

US3182065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:38:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-03T18:21:13', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'a8a6668f-150e-406b-8eb6-8eb5cc05fa13' User entered '03 Aug 2020 18:21'	System	03 Aug 2020 22:21:17
	System	03 Aug 2020 22:21:17

US3182065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:38:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '03 Aug 2020 12:00'	System	31 Jul 2020 21:28:45

US3182065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:38:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '04 Aug 2020 11:59'	System	31 Jul 2020 21:28:45

US3182065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
Data entry locked.	System	31 Jul 2020 21:28:45
User entered 'Day 7'	System	31 Jul 2020 21:28:45

US3182065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:38:18

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-04T23:56:46', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'f4c61008-6702-40fc-9114-ba9630a7a196'	System	05 Aug 2020 03:56:59
User entered 'None (1)'	System	05 Aug 2020 03:56:59

US3182065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:38:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-04T23:56:49', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'f4c61008-6702-40fc-9114-ba9630a7a196'	System	05 Aug 2020 03:56:59
User entered 'No (N)'	System	05 Aug 2020 03:56:59

US3182065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:38:18

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-04T23:56:51', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'f4c61008-6702-40fc-9114-ba9630a7a196' User entered 'No (N)'	System	05 Aug 2020 03:56:59
	System	05 Aug 2020 03:56:59

US3182065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:38:18

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-04T23:56:54', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'f4c61008-6702-40fc-9114-ba9630a7a196'	System	05 Aug 2020 03:56:59
User entered 'None (1)'	System	05 Aug 2020 03:56:59

US3182065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:38:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-04T23:56:57', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'f4c61008-6702-40fc-9114-ba9630a7a196'	System	05 Aug 2020 03:56:59
User entered '04 Aug 2020 23:56'	System	05 Aug 2020 03:56:59

US3182065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:38:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '04 Aug 2020 12:00'	System	31 Jul 2020 21:28:45

US3182065

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:38:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '05 Aug 2020 11:59'	System	31 Jul 2020 21:28:45

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
Data entry locked.	System	31 Jul 2020 21:28:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Jul 2020 21:28:45

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:38:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:38:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:38:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:38:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:38:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:38:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:38:18

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:38:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:38:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '29 Jul 2020 16:47'	System	31 Jul 2020 21:28:45

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:38:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '29 Jul 2020 19:17'	System	31 Jul 2020 21:28:45

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
Data entry locked.	System	31 Jul 2020 21:28:45
User entered 'Day 1, after vaccination (at home)'	System	31 Jul 2020 21:28:45

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:38:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:38:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:38:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:38:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:38:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:38:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:38:18

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:38:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:38:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '29 Jul 2020 20:12'	System	31 Jul 2020 21:28:45

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:38:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '30 Jul 2020 11:59'	System	31 Jul 2020 21:28:45

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
Data entry locked.	System	31 Jul 2020 21:28:45
User entered 'Day 2'	System	31 Jul 2020 21:28:45

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:38:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:38:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:38:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:38:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:38:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:38:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:38:18

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:38:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:38:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '30 Jul 2020 12:00'	System	31 Jul 2020 21:28:45

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:38:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '31 Jul 2020 11:59'	System	31 Jul 2020 21:28:45

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
Data entry locked.	System	31 Jul 2020 21:28:45
User entered 'Day 3'	System	31 Jul 2020 21:28:45

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:38:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-07-31T18:32:17', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '3cc286b4-fe9a-47df-bf41-e0cf1288b752'	System	31 Jul 2020 22:32:43
User entered 'No interference with activity (1)'	System	31 Jul 2020 22:32:43

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:38:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-07-31T18:32:21', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '3cc286b4-fe9a-47df-bf41-e0cf1288b752' User entered 'None (0)'	System	31 Jul 2020 22:32:43
	System	31 Jul 2020 22:32:43

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:38:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-07-31T18:32:24', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '3cc286b4-fe9a-47df-bf41-e0cf1288b752' User entered 'None (0)'	System	31 Jul 2020 22:32:43
	System	31 Jul 2020 22:32:43

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:38:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-07-31T18:32:27', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '3cc286b4-fe9a-47df-bf41-e0cf1288b752' User entered 'None (0)'	System	31 Jul 2020 22:32:43
	System	31 Jul 2020 22:32:43

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:38:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-07-31T18:32:30', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '3cc286b4-fe9a-47df-bf41-e0cf1288b752' User entered 'None (0)'	System	31 Jul 2020 22:32:43
	System	31 Jul 2020 22:32:43

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:38:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-07-31T18:32:32', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '3cc286b4-fe9a-47df-bf41-e0cf1288b752' User entered 'None (0)'	System	31 Jul 2020 22:32:43
	System	31 Jul 2020 22:32:43

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:38:18

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-07-31T18:32:36', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '3cc286b4-fe9a-47df-bf41-e0cf1288b752' User entered 'No (N)'	System	31 Jul 2020 22:32:43
	System	31 Jul 2020 22:32:43

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:38:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-07-31T18:32:39', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '3cc286b4-fe9a-47df-bf41-e0cf1288b752'	System	31 Jul 2020 22:32:43
User entered '31 Jul 2020 18:32'	System	31 Jul 2020 22:32:43

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:38:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '31 Jul 2020 12:00'	System	31 Jul 2020 21:28:45

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:38:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '01 Aug 2020 11:59'	System	31 Jul 2020 21:28:45

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
Data entry locked.	System	31 Jul 2020 21:28:45
User entered 'Day 4'	System	31 Jul 2020 21:28:45

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:38:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-01T19:23:25', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '9c353754-21ab-41b5-aae5-e6f3652a753f' User entered 'None (0)'	System	01 Aug 2020 23:23:46
	System	01 Aug 2020 23:23:46

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:38:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-01T19:23:28', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '9c353754-21ab-41b5-aae5-e6f3652a753f' User entered 'None (0)'	System	01 Aug 2020 23:23:46
	System	01 Aug 2020 23:23:46

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:38:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-01T19:23:30', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '9c353754-21ab-41b5-aae5-e6f3652a753f' User entered 'None (0)'	System	01 Aug 2020 23:23:46
	System	01 Aug 2020 23:23:46

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:38:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-01T19:23:33', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '9c353754-21ab-41b5-aae5-e6f3652a753f' User entered 'None (0)'	System	01 Aug 2020 23:23:46
	System	01 Aug 2020 23:23:46

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:38:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-01T19:23:35', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '9c353754-21ab-41b5-aae5-e6f3652a753f' User entered 'None (0)'	System	01 Aug 2020 23:23:46
	System	01 Aug 2020 23:23:46

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:38:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-01T19:23:37', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '9c353754-21ab-41b5-aae5-e6f3652a753f' User entered 'None (0)'	System	01 Aug 2020 23:23:46
	System	01 Aug 2020 23:23:46

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:38:18

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-01T19:23:40', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '9c353754-21ab-41b5-aae5-e6f3652a753f' User entered 'No (N)'	System	01 Aug 2020 23:23:46
	System	01 Aug 2020 23:23:46

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:38:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-01T19:23:43', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '9c353754-21ab-41b5-aae5-e6f3652a753f' User entered '01 Aug 2020 19:23'	System	01 Aug 2020 23:23:46
	System	01 Aug 2020 23:23:46

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:38:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '01 Aug 2020 12:00'	System	31 Jul 2020 21:28:45

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:38:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '02 Aug 2020 11:59'	System	31 Jul 2020 21:28:45

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
Data entry locked.	System	31 Jul 2020 21:28:45
User entered 'Day 5'	System	31 Jul 2020 21:28:45

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:38:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-02T13:07:33', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'd8f1405b-e665-4c7e-9dea-81e0ff7a89ef' User entered 'None (0)'	System	02 Aug 2020 17:07:58
	System	02 Aug 2020 17:07:58

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:38:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-02T13:07:35', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'd8f1405b-e665-4c7e-9dea-81e0ff7a89ef' User entered 'None (0)'	System	02 Aug 2020 17:07:58
	System	02 Aug 2020 17:07:58

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:38:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-02T13:07:38', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'd8f1405b-e665-4c7e-9dea-81e0ff7a89ef' User entered 'None (0)'	System	02 Aug 2020 17:07:58
	System	02 Aug 2020 17:07:58

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:38:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-02T13:07:41', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'd8f1405b-e665-4c7e-9dea-81e0ff7a89ef' User entered 'None (0)'	System	02 Aug 2020 17:07:58
	System	02 Aug 2020 17:07:58

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:38:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-02T13:07:44', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'd8f1405b-e665-4c7e-9dea-81e0ff7a89ef' User entered 'None (0)'	System	02 Aug 2020 17:07:58
	System	02 Aug 2020 17:07:58

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:38:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-02T13:07:47', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'd8f1405b-e665-4c7e-9dea-81e0ff7a89ef' User entered 'None (0)'	System	02 Aug 2020 17:07:58
	System	02 Aug 2020 17:07:58

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:38:18

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-02T13:07:50', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'd8f1405b-e665-4c7e-9dea-81e0ff7a89ef' User entered 'No (N)'	System	02 Aug 2020 17:07:58
	System	02 Aug 2020 17:07:58

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:38:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-02T13:07:56', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'd8f1405b-e665-4c7e-9dea-81e0ff7a89ef' User entered '02 Aug 2020 13:07'	System	02 Aug 2020 17:07:58
	System	02 Aug 2020 17:07:58

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:38:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '02 Aug 2020 12:00'	System	31 Jul 2020 21:28:45

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:38:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '03 Aug 2020 11:59'	System	31 Jul 2020 21:28:45

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
Data entry locked.	System	31 Jul 2020 21:28:45
User entered 'Day 6'	System	31 Jul 2020 21:28:45

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:38:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-03T18:21:17', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'e927551d-21ca-4f51-8aa5-12cc285cc411' User entered 'None (0)'	System	03 Aug 2020 22:21:40
	System	03 Aug 2020 22:21:40

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:38:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-03T18:21:20', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'e927551d-21ca-4f51-8aa5-12cc285cc411' User entered 'None (0)'	System	03 Aug 2020 22:21:40
	System	03 Aug 2020 22:21:40

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:38:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-03T18:21:24', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'e927551d-21ca-4f51-8aa5-12cc285cc411' User entered 'None (0)'	System	03 Aug 2020 22:21:40
	System	03 Aug 2020 22:21:40

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:38:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-03T18:21:27', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'e927551d-21ca-4f51-8aa5-12cc285cc411' User entered 'None (0)'	System	03 Aug 2020 22:21:40
	System	03 Aug 2020 22:21:40

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:38:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-03T18:21:30', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'e927551d-21ca-4f51-8aa5-12cc285cc411' User entered 'None (0)'	System	03 Aug 2020 22:21:40
	System	03 Aug 2020 22:21:40

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:38:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-03T18:21:33', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'e927551d-21ca-4f51-8aa5-12cc285cc411' User entered 'None (0)'	System	03 Aug 2020 22:21:40
	System	03 Aug 2020 22:21:40

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:38:18

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-03T18:21:36', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'e927551d-21ca-4f51-8aa5-12cc285cc411' User entered 'No (N)'	System	03 Aug 2020 22:21:40
	System	03 Aug 2020 22:21:40

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:38:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-03T18:21:38', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'e927551d-21ca-4f51-8aa5-12cc285cc411' User entered '03 Aug 2020 18:21'	System	03 Aug 2020 22:21:40
	System	03 Aug 2020 22:21:40

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:38:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '03 Aug 2020 12:00'	System	31 Jul 2020 21:28:45

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:38:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '04 Aug 2020 11:59'	System	31 Jul 2020 21:28:45

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
Data entry locked.	System	31 Jul 2020 21:28:45
User entered 'Day 7'	System	31 Jul 2020 21:28:45

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:38:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-04T23:57:02', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '549f0306-5a7c-4143-b9ca-b01fd7f9da8a' User entered 'None (0)'	System	05 Aug 2020 03:57:22
	System	05 Aug 2020 03:57:22

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:38:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-04T23:57:04', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '549f0306-5a7c-4143-b9ca-b01fd7f9da8a' User entered 'None (0)'	System	05 Aug 2020 03:57:22
	System	05 Aug 2020 03:57:22

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:38:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-04T23:57:07', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '549f0306-5a7c-4143-b9ca-b01fd7f9da8a' User entered 'None (0)'	System	05 Aug 2020 03:57:22
	System	05 Aug 2020 03:57:22

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:38:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-04T23:57:09', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '549f0306-5a7c-4143-b9ca-b01fd7f9da8a' User entered 'None (0)'	System	05 Aug 2020 03:57:22
	System	05 Aug 2020 03:57:22

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:38:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-04T23:57:12', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '549f0306-5a7c-4143-b9ca-b01fd7f9da8a' User entered 'None (0)'	System	05 Aug 2020 03:57:22
	System	05 Aug 2020 03:57:22

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:38:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-04T23:57:14', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '549f0306-5a7c-4143-b9ca-b01fd7f9da8a' User entered 'None (0)'	System	05 Aug 2020 03:57:22
	System	05 Aug 2020 03:57:22

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:38:18

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-04T23:57:17', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '549f0306-5a7c-4143-b9ca-b01fd7f9da8a' User entered 'No (N)'	System	05 Aug 2020 03:57:22
	System	05 Aug 2020 03:57:22

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:38:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-04T23:57:20', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '549f0306-5a7c-4143-b9ca-b01fd7f9da8a' User entered '04 Aug 2020 23:57'	System	05 Aug 2020 03:57:22
	System	05 Aug 2020 03:57:22

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:38:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '04 Aug 2020 12:00'	System	31 Jul 2020 21:28:45

US3182065

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:38:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '05 Aug 2020 11:59'	System	31 Jul 2020 21:28:45

US3182065

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	19 Feb 2021 17:59:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 19:06:39
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:01:51

US3182065

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:18

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	19 Feb 2021 17:59:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 19:06:39
User entered '05 Aug 2020'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:01:51

US3182065

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	19 Feb 2021 17:59:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 19:06:39
User entered 'Contact Made (CONTACT MADE)'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:01:51

US3182065

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	19 Feb 2021 17:59:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 19:06:39
User entered empty.	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:01:51

US3182065

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:38:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	19 Feb 2021 17:59:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 19:06:45
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	11 Aug 2020 19:01:55

US3182065

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:38:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User entered 'I'	System	11 Aug 2020 19:01:55

US3182065

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	19 Feb 2021 17:59:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:27:37
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	31 Aug 2020 18:24:32

US3182065

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:18

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	19 Feb 2021 17:59:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:27:37
User entered '12 Aug 2020'	Cassie Uminski (b) (4) (b) (4)	31 Aug 2020 18:24:32

US3182065

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	19 Feb 2021 17:59:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:27:37
User entered 'Contact Made (CONTACT MADE)'	Cassie Uminski (b) (4) (b) (4)	31 Aug 2020 18:24:32

US3182065

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	19 Feb 2021 17:59:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:27:37
User entered empty.	Cassie Uminski (b) (4) (b) (4)	31 Aug 2020 18:24:32

US3182065

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:38:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	19 Feb 2021 17:59:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:27:42
User entered 'Yes (Y)'	Alec Ireland (b) (4) (b) (4)	24 Aug 2020 18:27:13

US3182065

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:38:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User entered 'I'	System	24 Aug 2020 18:27:13

US3182065

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	19 Feb 2021 17:59:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:27:55
User entered 'Yes (Y)'	Alec Ireland (b) (4) (b) (4)	24 Aug 2020 18:27:22

US3182065

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:18

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	19 Feb 2021 17:59:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:27:55
User entered '19 Aug 2020'	Alec Ireland (b) (4) (b) (4)	24 Aug 2020 18:27:22

US3182065

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	19 Feb 2021 17:59:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:27:55
User entered 'Contact Made (CONTACT MADE)'	Alec Ireland (b) (4) (b) (4)	24 Aug 2020 18:27:22

US3182065

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	19 Feb 2021 17:59:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:27:55
User entered empty.	Alec Ireland (b) (4) (b) (4)	24 Aug 2020 18:27:22

US3182065

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:38:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	19 Feb 2021 17:59:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:28:05
User entered 'Yes (Y)'	Alec Ireland (b) (4) (b) (4)	24 Aug 2020 18:27:26

US3182065

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:38:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User entered 'I'	System	24 Aug 2020 18:27:26

US3182065

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:38:18

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:33:28
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	31 Aug 2020 18:26:19

US3182065

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:38:18

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:33:28
User entered '28 Aug 2020'	Cassie Uminski (b) (4) (b) (4)	31 Aug 2020 18:26:19

US3182065

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:38:18

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:33:28
User entered 'Clinic (Clinic)'	Cassie Uminski (b) (4) (b) (4)	31 Aug 2020 18:26:19

US3182065

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:38:18

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User entered 'VISIT2'	System	31 Aug 2020 18:26:19

US3182065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:18

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User accepted default value 'Pre-Dose (PREDOSE)'	Cassie Uminski (b) (4)	31 Aug 2020 18:27:06
	(b) (4)	

US3182065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:33:37
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	31 Aug 2020 18:27:06

US3182065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:33:37
User entered '28 Aug 2020'	Cassie Uminski (b) (4) (b) (4)	31 Aug 2020 18:27:06

US3182065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:18

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:33:37
User entered '11:25'	Cassie Uminski (b) (4) (b) (4)	31 Aug 2020 18:27:06

US3182065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:18

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User entered '28 Aug 2020 11:25'	System	31 Aug 2020 18:27:06

US3182065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:33:37
User entered '98.4' F	Cassie Uminski (b) (4) (b) (4)	31 Aug 2020 18:27:06

US3182065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:33:37
User entered 'Oral (Oral)'	Cassie Uminski (b) (4) (b) (4)	31 Aug 2020 18:27:06

US3182065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:33:37
User entered empty.	Cassie Uminski (b) (4) (b) (4)	31 Aug 2020 18:27:06

US3182065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:33:37
User entered '94'	Cassie Uminski (b) (4) (b) (4)	31 Aug 2020 18:27:06

US3182065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User entered 'bpm'	System	31 Aug 2020 18:27:06

US3182065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:18

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:33:37
User entered '16'	Cassie Uminski (b) (4) (b) (4)	31 Aug 2020 18:27:06

US3182065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User entered 'breaths/min'	System	31 Aug 2020 18:27:06

US3182065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:18

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:33:37
User entered '119'	Cassie Uminski (b) (4) (b) (4)	31 Aug 2020 18:27:06

US3182065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User entered 'mmHg'	System	31 Aug 2020 18:27:06

US3182065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:33:37
User entered '78'	Cassie Uminski (b) (4) (b) (4)	31 Aug 2020 18:27:06

US3182065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:18

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User entered 'mmHg'	System	31 Aug 2020 18:27:06

US3182065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:18

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User accepted default value 'Post-Dose (POSTDOSE)'	Cassie Uminski (b) (4) (b) (4)	31 Aug 2020 18:27:06

US3182065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:33:37
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	31 Aug 2020 18:27:06

US3182065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:33:37
User entered '28 Aug 2020'	Cassie Uminski (b) (4) (b) (4)	31 Aug 2020 18:27:06

US3182065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:18

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:33:37
User entered '12:34'	Cassie Uminski (b) (4) (b) (4)	31 Aug 2020 18:27:06

US3182065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:18

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User entered '28 Aug 2020 12:34'	System	31 Aug 2020 18:27:06

US3182065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:33:37
User entered '98.2' F	Cassie Uminski (b) (4) (b) (4)	31 Aug 2020 18:27:06

US3182065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:33:37
User entered 'Oral (Oral)'	Cassie Uminski (b) (4) (b) (4)	31 Aug 2020 18:27:06

US3182065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:33:37
User entered empty.	Cassie Uminski (b) (4) (b) (4)	31 Aug 2020 18:27:06

US3182065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:33:37
User entered '83'	Cassie Uminski (b) (4) (b) (4)	31 Aug 2020 18:27:06

US3182065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User entered 'bpm'	System	31 Aug 2020 18:27:06

US3182065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:18

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:33:37
User entered '16'	Cassie Uminski (b) (4) (b) (4)	31 Aug 2020 18:27:06

US3182065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User entered 'breaths/min'	System	31 Aug 2020 18:27:06

US3182065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:33:37
User entered '106'	Cassie Uminski (b) (4) (b) (4)	31 Aug 2020 18:27:06

US3182065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User entered 'mmHg'	System	31 Aug 2020 18:27:06

US3182065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:33:37
User entered '73'	Cassie Uminski (b) (4) (b) (4)	31 Aug 2020 18:27:06

US3182065

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:18

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User entered 'mmHg'	System	31 Aug 2020 18:27:06

US3182065

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:38:18

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:34:43
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	31 Aug 2020 18:27:22

US3182065

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:38:18

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:34:43
User entered '28 Aug 2020'	Cassie Uminski (b) (4) (b) (4)	31 Aug 2020 18:27:22

US3182065

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:38:18

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:34:59
User entered 'Yes (Y)'	Amy Maroun (b) (4) (b) (4)	28 Aug 2020 16:02:48

US3182065

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:38:18

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:34:59
User entered empty.	Amy Maroun (b) (4) (b) (4)	28 Aug 2020 16:02:48

US3182065

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:38:18

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:34:59
User entered empty.	Amy Maroun (b) (4) (b) (4)	28 Aug 2020 16:02:48

US3182065

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:38:18

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User entered 'MRNA-1273 OR PLACEBO'	System	28 Aug 2020 16:02:48

US3182065

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:38:18

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:34:59
User entered '28 Aug 2020'	Amy Maroun (b) (4) (b) (4)	28 Aug 2020 16:02:48

US3182065

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:38:18

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:34:59
User entered '11:59'	Amy Maroun (b) (4) (b) (4)	28 Aug 2020 16:02:48

US3182065

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:38:18

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User entered '28 Aug 2020 11:59'	System	28 Aug 2020 16:02:48

US3182065

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:38:18

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:34:59
User entered 'Left Arm (LEFT ARM)'	Amy Maroun (b) (4) (b) (4)	28 Aug 2020 16:02:48

US3182065

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:38:18

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
DataPoint Verified.		12 Oct 2020 16:34:59
User entered 'ONCE'	System	28 Aug 2020 16:02:48

US3182065

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:38:18

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User entered 'INTRAMUSCULAR'	System	28 Aug 2020 16:02:48

US3182065

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:38:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:35:14
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	31 Aug 2020 18:28:01

US3182065

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:38:18

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:35:14
User entered '28 Aug 2020'	Cassie Uminski (b) (4) (b) (4)	31 Aug 2020 18:28:01

US3182065

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:38:18

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:35:14
User entered '11:44'	Cassie Uminski (b) (4) (b) (4)	31 Aug 2020 18:28:01

US3182065

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:38:18

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User entered '28 Aug 2020 11:44'	System	31 Aug 2020 18:28:01

US3182065

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:38:18

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:35:21
User entered '28 Aug 2020'	Cassie Uminski (b) (4) (b) (4)	31 Aug 2020 18:27:40

US3182065

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:38:18

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Cassie Uminski (b) (4)	31 Aug 2020 18:27:40

US3182065

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:38:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:35:21
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	31 Aug 2020 18:27:40

US3182065

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:38:18

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:35:21
User entered '11:40'	Cassie Uminski (b) (4) (b) (4)	31 Aug 2020 18:27:40

US3182065

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:38:18

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User entered '28 Aug 2020 11:40'	System	31 Aug 2020 18:27:40

US3182065

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:38:18

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Cassie Uminski (b) (4)	31 Aug 2020 18:27:40

US3182065

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:38:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:35:21
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	31 Aug 2020 18:27:40

US3182065

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:38:18

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:35:21
User entered empty.	Cassie Uminski (b) (4) (b) (4)	31 Aug 2020 18:27:40

US3182065

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:38:18

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User entered empty.	System	31 Aug 2020 18:27:40

US3182065

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:38:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:35:26
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	31 Aug 2020 18:28:05

US3182065

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:38:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User entered 'I'	System	31 Aug 2020 18:28:05

US3182065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
Data entry locked.	System	28 Aug 2020 16:02:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 16:02:48

US3182065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:38:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-28T12:35:47', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '6581fca4-4a52-4bd9-a6d2-9a4f252099e4' User entered 'Yes (Y)'	System	28 Aug 2020 16:36:19
	System	28 Aug 2020 16:36:19

US3182065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:38:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-28T12:36:09', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '6581fca4-4a52-4bd9-a6d2-9a4f252099e4' User entered '98.2'	System	28 Aug 2020 16:36:19
	System	28 Aug 2020 16:36:19

US3182065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:38:18

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-28T12:36:12', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '6581fca4-4a52-4bd9-a6d2-9a4f252099e4' User entered 'No (N)'	System	28 Aug 2020 16:36:19
	System	28 Aug 2020 16:36:19

US3182065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:38:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-28T12:36:16', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '6581fca4-4a52-4bd9-a6d2-9a4f252099e4' User entered '28 Aug 2020 12:36'	System	28 Aug 2020 16:36:19
	System	28 Aug 2020 16:36:19

US3182065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:38:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '28 Aug 2020 12:19'	System	28 Aug 2020 16:02:48

US3182065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:38:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '28 Aug 2020 14:49'	System	28 Aug 2020 16:02:48

US3182065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
Data entry locked.	System	28 Aug 2020 16:02:48
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 16:02:48

US3182065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:38:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-28T21:28:47', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'e0be5802-ab68-4981-be95-0f0299bcc680' User entered 'Yes (Y)'	System	29 Aug 2020 01:29:11
	System	29 Aug 2020 01:29:11

US3182065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:38:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-28T21:29:00', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'e0be5802-ab68-4981-be95-0f0299bcc680' User entered '96.5'	System	29 Aug 2020 01:29:11
	System	29 Aug 2020 01:29:11

US3182065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:38:18

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-28T21:29:03', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'e0be5802-ab68-4981-be95-0f0299bcc680'	System	29 Aug 2020 01:29:11
User entered 'No (N)'	System	29 Aug 2020 01:29:11

US3182065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:38:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-28T21:29:10', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'e0be5802-ab68-4981-be95-0f0299bcc680' User entered '28 Aug 2020 21:29'	System	29 Aug 2020 01:29:11
	System	29 Aug 2020 01:29:11

US3182065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:38:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '28 Aug 2020 15:44'	System	28 Aug 2020 16:02:48

US3182065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:38:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 16:02:48

US3182065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
Data entry locked.	System	28 Aug 2020 16:02:48
User entered 'Day 2'	System	28 Aug 2020 16:02:48

US3182065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:38:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-29T23:56:13', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '85763dee-18d4-4e1f-98a5-dfd4183792d2' User entered 'Yes (Y)'	System	30 Aug 2020 03:56:30
	System	30 Aug 2020 03:56:30

US3182065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:38:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-29T23:56:21', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '85763dee-18d4-4e1f-98a5-dfd4183792d2' User entered '96.0'	System	30 Aug 2020 03:56:30
	System	30 Aug 2020 03:56:30

US3182065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:38:18

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-29T23:56:24', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '85763dee-18d4-4e1f-98a5-dfd4183792d2' User entered 'No (N)'	System	30 Aug 2020 03:56:30
	System	30 Aug 2020 03:56:30

US3182065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:38:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-29T23:56:29', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '85763dee-18d4-4e1f-98a5-dfd4183792d2' User entered '29 Aug 2020 23:56'	System	30 Aug 2020 03:56:30
	System	30 Aug 2020 03:56:30

US3182065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:38:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 16:02:48

US3182065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:38:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 16:02:48

US3182065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
Data entry locked.	System	28 Aug 2020 16:02:48
User entered 'Day 3'	System	28 Aug 2020 16:02:48

US3182065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:38:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-30T18:53:59', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '14413474-8845-48d9-b3ec-955495a9d36f' User entered 'Yes (Y)'	System	30 Aug 2020 22:54:28
	System	30 Aug 2020 22:54:28

US3182065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:38:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-30T18:54:07', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '14413474-8845-48d9-b3ec-955495a9d36f' User entered '96.1'	System	30 Aug 2020 22:54:28
	System	30 Aug 2020 22:54:28

US3182065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:38:18

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-30T18:54:16', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '14413474-8845-48d9-b3ec-955495a9d36f' User entered 'Yes (Y)'	System	30 Aug 2020 22:54:28
	System	30 Aug 2020 22:54:28

US3182065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:38:18

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Updated' (Site from System).	(b) (4)	29 Sep 2020 02:41:10
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Cassie Uminski (b) (4)	25 Sep 2020 16:48:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-30T18:54:21', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '14413474-8845-48d9-b3ec-955495a9d36f'	(b) (4)	
User entered '1'	System	30 Aug 2020 22:54:28
	System	30 Aug 2020 22:54:28
	System	30 Aug 2020 22:54:28

US3182065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:38:18

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-30T18:54:21', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '14413474-8845-48d9-b3ec-955495a9d36f' User entered '0'	System	30 Aug 2020 22:54:28
	System	30 Aug 2020 22:54:28

US3182065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:38:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-30T18:54:25', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '14413474-8845-48d9-b3ec-955495a9d36f' User entered '30 Aug 2020 18:54'	System	30 Aug 2020 22:54:28
	System	30 Aug 2020 22:54:28

US3182065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:38:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 16:02:48

US3182065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:38:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 16:02:48

US3182065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
Data entry locked.	System	28 Aug 2020 16:02:48
User entered 'Day 4'	System	28 Aug 2020 16:02:48

US3182065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:38:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-31T23:48:16', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'c471d5c1-57bd-4dee-bd3b-eff7ccf97522'	System	01 Sep 2020 03:48:47
User entered 'Yes (Y)'	System	01 Sep 2020 03:48:47

US3182065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:38:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-31T23:48:37', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'c471d5c1-57bd-4dee-bd3b-eff7ccf97522' User entered '95.7'	System	01 Sep 2020 03:48:47
	System	01 Sep 2020 03:48:47

US3182065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:38:18

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-31T23:48:40', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'c471d5c1-57bd-4dee-bd3b-eff7ccf97522'	System	01 Sep 2020 03:48:47
User entered 'No (N)'	System	01 Sep 2020 03:48:47

US3182065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:38:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-31T23:48:44', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'c471d5c1-57bd-4dee-bd3b-eff7ccf97522' User entered '31 Aug 2020 23:48'	System	01 Sep 2020 03:48:47
	System	01 Sep 2020 03:48:47

US3182065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:38:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 16:02:48

US3182065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:38:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 16:02:48

US3182065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
Data entry locked.	System	28 Aug 2020 16:02:48
User entered 'Day 5'	System	28 Aug 2020 16:02:48

US3182065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:38:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-09-02T04:06:18', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '41457caa-c0ad-4c25-a323-37af3c3bf927'	System	02 Sep 2020 08:06:38
User entered 'Yes (Y)'	System	02 Sep 2020 08:06:38

US3182065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:38:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-09-02T04:06:29', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '41457caa-c0ad-4c25-a323-37af3c3bf927' User entered '95.7'	System	02 Sep 2020 08:06:38
	System	02 Sep 2020 08:06:38

US3182065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:38:18

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-09-02T04:06:32', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '41457caa-c0ad-4c25-a323-37af3c3bf927'	System	02 Sep 2020 08:06:38
User entered 'No (N)'	System	02 Sep 2020 08:06:38

US3182065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:38:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-09-02T04:06:34', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '41457caa-c0ad-4c25-a323-37af3c3bf927' User entered '02 Sep 2020 04:06'	System	02 Sep 2020 08:06:38
	System	02 Sep 2020 08:06:38

US3182065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:38:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 16:02:48

US3182065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:38:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 16:02:48

US3182065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
Data entry locked.	System	28 Aug 2020 16:02:48
User entered 'Day 6'	System	28 Aug 2020 16:02:48

US3182065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:38:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-09-03T00:05:48', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '2931de39-0d28-47f9-a556-6d52492ab0f4' User entered 'Yes (Y)'	System	03 Sep 2020 04:06:04
	System	03 Sep 2020 04:06:04

US3182065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:38:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-09-03T00:05:56', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '2931de39-0d28-47f9-a556-6d52492ab0f4' User entered '95.8'	System	03 Sep 2020 04:06:04
	System	03 Sep 2020 04:06:04

US3182065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:38:18

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-09-03T00:05:59', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '2931de39-0d28-47f9-a556-6d52492ab0f4' User entered 'No (N)'	System	03 Sep 2020 04:06:04
	System	03 Sep 2020 04:06:04

US3182065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:38:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-09-03T00:06:02', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '2931de39-0d28-47f9-a556-6d52492ab0f4' User entered '03 Sep 2020 00:06'	System	03 Sep 2020 04:06:04
	System	03 Sep 2020 04:06:04

US3182065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:38:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 16:02:48

US3182065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:38:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 16:02:48

US3182065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
Data entry locked.	System	28 Aug 2020 16:02:48
User entered 'Day 7'	System	28 Aug 2020 16:02:48

US3182065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:38:18

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-09-03T16:04:50', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '3e986f3c-32e3-42fb-bdea-4bd0cfa177f2' User entered 'Yes (Y)'	System	03 Sep 2020 20:05:12
	System	03 Sep 2020 20:05:12

US3182065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:38:18

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-09-03T16:04:58', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '3e986f3c-32e3-42fb-bdea-4bd0cfa177f2' User entered '99.0'	System	03 Sep 2020 20:05:12
	System	03 Sep 2020 20:05:12

US3182065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:38:18

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-09-03T16:05:01', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '3e986f3c-32e3-42fb-bdea-4bd0cfa177f2'	System	03 Sep 2020 20:05:12
User entered 'No (N)'	System	03 Sep 2020 20:05:12

US3182065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:38:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-09-03T16:05:07', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '3e986f3c-32e3-42fb-bdea-4bd0cfa177f2'	System	03 Sep 2020 20:05:12
User entered '03 Sep 2020 16:05'	System	03 Sep 2020 20:05:12

US3182065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:38:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 16:02:48

US3182065

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:38:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 16:02:48

US3182065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
Data entry locked.	System	28 Aug 2020 16:02:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 16:02:48

US3182065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:38:18

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-28T12:36:23', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '6ead3a15-4374-45de-b495-5d9e3bbabed4' User entered 'None (1)'	System	28 Aug 2020 16:36:40
	System	28 Aug 2020 16:36:40

US3182065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:38:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-28T12:36:27', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '6ead3a15-4374-45de-b495-5d9e3bbabed4' User entered 'No (N)'	System	28 Aug 2020 16:36:40
	System	28 Aug 2020 16:36:40

US3182065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:38:18

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-28T12:36:30', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '6ead3a15-4374-45de-b495-5d9e3bbabed4' User entered 'No (N)'	System	28 Aug 2020 16:36:40
	System	28 Aug 2020 16:36:40

US3182065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:38:18

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-28T12:36:35', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '6ead3a15-4374-45de-b495-5d9e3bbabed4' User entered 'None (1)'	System	28 Aug 2020 16:36:40
	System	28 Aug 2020 16:36:40

US3182065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:38:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-28T12:36:39', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '6ead3a15-4374-45de-b495-5d9e3bbabed4' User entered '28 Aug 2020 12:36'	System	28 Aug 2020 16:36:40
	System	28 Aug 2020 16:36:40

US3182065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:38:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '28 Aug 2020 12:19'	System	28 Aug 2020 16:02:48

US3182065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:38:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '28 Aug 2020 14:49'	System	28 Aug 2020 16:02:48

US3182065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
Data entry locked.	System	28 Aug 2020 16:02:48
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 16:02:48

US3182065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:38:18

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-28T21:29:18', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '6227e834-9a01-4db3-b596-155934cfa5a5' User entered 'None (1)'	System	29 Aug 2020 01:29:44
	System	29 Aug 2020 01:29:44

US3182065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:38:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-28T21:29:22', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '6227e834-9a01-4db3-b596-155934cfa5a5' User entered 'No (N)'	System	29 Aug 2020 01:29:44
	System	29 Aug 2020 01:29:44

US3182065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:38:18

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-28T21:29:26', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '6227e834-9a01-4db3-b596-155934cfa5a5' User entered 'No (N)'	System	29 Aug 2020 01:29:44
	System	29 Aug 2020 01:29:44

US3182065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:38:18

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-28T21:29:36', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '6227e834-9a01-4db3-b596-155934cfa5a5' User entered 'None (1)'	System	29 Aug 2020 01:29:44
	System	29 Aug 2020 01:29:44

US3182065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:38:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-28T21:29:40', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '6227e834-9a01-4db3-b596-155934cfa5a5' User entered '28 Aug 2020 21:29'	System	29 Aug 2020 01:29:44
	System	29 Aug 2020 01:29:44

US3182065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:38:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '28 Aug 2020 15:44'	System	28 Aug 2020 16:02:48

US3182065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:38:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 16:02:48

US3182065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
Data entry locked.	System	28 Aug 2020 16:02:48
User entered 'Day 2'	System	28 Aug 2020 16:02:48

US3182065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:38:18

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-29T23:56:35', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '563fb720-9e7e-4c03-911a-e8b414a4b28c' User entered 'None (1)'	System	30 Aug 2020 03:56:59
	System	30 Aug 2020 03:56:59

US3182065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:38:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-29T23:56:39', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '563fb720-9e7e-4c03-911a-e8b414a4b28c' User entered 'No (N)'	System	30 Aug 2020 03:56:59
	System	30 Aug 2020 03:56:59

US3182065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:38:18

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-29T23:56:49', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '563fb720-9e7e-4c03-911a-e8b414a4b28c' User entered 'No (N)'	System	30 Aug 2020 03:56:59
	System	30 Aug 2020 03:56:59

US3182065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:38:18

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-29T23:56:53', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '563fb720-9e7e-4c03-911a-e8b414a4b28c' User entered 'None (1)'	System	30 Aug 2020 03:56:59
	System	30 Aug 2020 03:56:59

US3182065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:38:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-29T23:56:57', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '563fb720-9e7e-4c03-911a-e8b414a4b28c' User entered '29 Aug 2020 23:56'	System	30 Aug 2020 03:56:59
	System	30 Aug 2020 03:56:59

US3182065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:38:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 16:02:48

US3182065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:38:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 16:02:48

US3182065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
Data entry locked.	System	28 Aug 2020 16:02:48
User entered 'Day 3'	System	28 Aug 2020 16:02:48

US3182065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:38:18

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-30T18:54:30', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '56aa860b-dd30-4047-92d3-fdd70d5cd3a3' User entered 'None (1)'	System	30 Aug 2020 22:54:51
	System	30 Aug 2020 22:54:51

US3182065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:38:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-30T18:54:34', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '56aa860b-dd30-4047-92d3-fdd70d5cd3a3' User entered 'No (N)'	System	30 Aug 2020 22:54:51
	System	30 Aug 2020 22:54:51

US3182065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:38:18

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-30T18:54:36', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '56aa860b-dd30-4047-92d3-fdd70d5cd3a3' User entered 'No (N)'	System	30 Aug 2020 22:54:51
	System	30 Aug 2020 22:54:51

US3182065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:38:18

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-30T18:54:44', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '56aa860b-dd30-4047-92d3-fdd70d5cd3a3' User entered 'None (1)'	System	30 Aug 2020 22:54:51
	System	30 Aug 2020 22:54:51

US3182065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:38:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-30T18:54:48', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '56aa860b-dd30-4047-92d3-fdd70d5cd3a3' User entered '30 Aug 2020 18:54'	System	30 Aug 2020 22:54:51
	System	30 Aug 2020 22:54:51

US3182065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:38:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 16:02:48

US3182065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:38:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 16:02:48

US3182065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
Data entry locked.	System	28 Aug 2020 16:02:48
User entered 'Day 4'	System	28 Aug 2020 16:02:48

US3182065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:38:18

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-31T23:48:57', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'dd148fc1-c82d-4385-bba9-a85e727336ca' User entered 'None (1)'	System	01 Sep 2020 03:49:08
	System	01 Sep 2020 03:49:08

US3182065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:38:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-31T23:48:55', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'dd148fc1-c82d-4385-bba9-a85e727336ca' User entered 'No (N)'	System	01 Sep 2020 03:49:08
	System	01 Sep 2020 03:49:08

US3182065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:38:18

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-31T23:49:00', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'dd148fc1-c82d-4385-bba9-a85e727336ca' User entered 'No (N)'	System	01 Sep 2020 03:49:08
	System	01 Sep 2020 03:49:08

US3182065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:38:18

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-31T23:49:02', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'dd148fc1-c82d-4385-bba9-a85e727336ca' User entered 'None (1)'	System	01 Sep 2020 03:49:08
	System	01 Sep 2020 03:49:08

US3182065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:38:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-31T23:49:05', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'dd148fc1-c82d-4385-bba9-a85e727336ca' User entered '31 Aug 2020 23:49'	System	01 Sep 2020 03:49:08
	System	01 Sep 2020 03:49:08

US3182065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:38:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 16:02:48

US3182065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:38:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 16:02:48

US3182065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
Data entry locked.	System	28 Aug 2020 16:02:48
User entered 'Day 5'	System	28 Aug 2020 16:02:48

US3182065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:38:18

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-09-02T04:06:39', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'a2f34fba-237d-4496-8430-d6df90745687' User entered 'None (1)'	System	02 Sep 2020 08:06:50
	System	02 Sep 2020 08:06:50

US3182065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:38:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-09-02T04:06:41', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'a2f34fba-237d-4496-8430-d6df90745687' User entered 'No (N)'	System	02 Sep 2020 08:06:50
	System	02 Sep 2020 08:06:50

US3182065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:38:18

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-09-02T04:06:43', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'a2f34fba-237d-4496-8430-d6df90745687' User entered 'No (N)'	System	02 Sep 2020 08:06:50
	System	02 Sep 2020 08:06:50

US3182065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:38:18

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-09-02T04:06:45', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'a2f34fba-237d-4496-8430-d6df90745687' User entered 'None (1)'	System	02 Sep 2020 08:06:50
	System	02 Sep 2020 08:06:50

US3182065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:38:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-09-02T04:06:48', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'a2f34fba-237d-4496-8430-d6df90745687' User entered '02 Sep 2020 04:06'	System	02 Sep 2020 08:06:50
	System	02 Sep 2020 08:06:50

US3182065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:38:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 16:02:48

US3182065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:38:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 16:02:48

US3182065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
Data entry locked.	System	28 Aug 2020 16:02:48
User entered 'Day 6'	System	28 Aug 2020 16:02:48

US3182065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:38:18

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-09-03T00:06:06', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'f8a83523-81b1-427d-a355-b35886dde44e' User entered 'None (1)'	System	03 Sep 2020 04:06:22
	System	03 Sep 2020 04:06:22

US3182065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:38:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-09-03T00:06:09', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'f8a83523-81b1-427d-a355-b35886dde44e' User entered 'No (N)'	System	03 Sep 2020 04:06:22
	System	03 Sep 2020 04:06:22

US3182065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:38:18

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-09-03T00:06:11', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'f8a83523-81b1-427d-a355-b35886dde44e' User entered 'No (N)'	System	03 Sep 2020 04:06:22
	System	03 Sep 2020 04:06:22

US3182065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:38:18

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-09-03T00:06:14', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'f8a83523-81b1-427d-a355-b35886dde44e' User entered 'None (1)'	System	03 Sep 2020 04:06:22
	System	03 Sep 2020 04:06:22

US3182065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:38:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-09-03T00:06:19', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'f8a83523-81b1-427d-a355-b35886dde44e' User entered '03 Sep 2020 00:06'	System	03 Sep 2020 04:06:22
	System	03 Sep 2020 04:06:22

US3182065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:38:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 16:02:48

US3182065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:38:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 16:02:48

US3182065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
Data entry locked.	System	28 Aug 2020 16:02:48
User entered 'Day 7'	System	28 Aug 2020 16:02:48

US3182065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:38:18

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-09-03T16:05:15', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'ab28cfd7-82d9-47c6-a48a-51d40c35ca2a' User entered 'None (1)'	System	03 Sep 2020 20:05:32
	System	03 Sep 2020 20:05:32

US3182065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:38:18

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-09-03T16:05:19', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'ab28cfd7-82d9-47c6-a48a-51d40c35ca2a' User entered 'No (N)'	System	03 Sep 2020 20:05:32
	System	03 Sep 2020 20:05:32

US3182065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:38:18

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-09-03T16:05:22', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'ab28cfd7-82d9-47c6-a48a-51d40c35ca2a' User entered 'No (N)'	System	03 Sep 2020 20:05:32
	System	03 Sep 2020 20:05:32

US3182065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:38:18

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-09-03T16:05:27', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'ab28cfd7-82d9-47c6-a48a-51d40c35ca2a' User entered 'None (1)'	System	03 Sep 2020 20:05:32
	System	03 Sep 2020 20:05:32

US3182065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:38:18

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-09-03T16:05:30', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'ab28cfd7-82d9-47c6-a48a-51d40c35ca2a' User entered '03 Sep 2020 16:05'	System	03 Sep 2020 20:05:32
	System	03 Sep 2020 20:05:32

US3182065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:38:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 16:02:48

US3182065

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:38:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 16:02:48

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
Data entry locked.	System	28 Aug 2020 16:02:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 16:02:48

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:38:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-28T12:36:44', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '5cdd8fc5-86cc-4a25-b5f1-089f54540e37' User entered 'None (0)'	System	28 Aug 2020 16:37:05
	System	28 Aug 2020 16:37:05

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:38:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-28T12:36:46', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '5cdd8fc5-86cc-4a25-b5f1-089f54540e37' User entered 'None (0)'	System	28 Aug 2020 16:37:05
	System	28 Aug 2020 16:37:05

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:38:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-28T12:36:48', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '5cdd8fc5-86cc-4a25-b5f1-089f54540e37' User entered 'None (0)'	System	28 Aug 2020 16:37:05
	System	28 Aug 2020 16:37:05

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:38:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-28T12:36:51', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '5cdd8fc5-86cc-4a25-b5f1-089f54540e37' User entered 'None (0)'	System	28 Aug 2020 16:37:05
	System	28 Aug 2020 16:37:05

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:38:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-28T12:36:53', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '5cdd8fc5-86cc-4a25-b5f1-089f54540e37' User entered 'None (0)'	System	28 Aug 2020 16:37:05
	System	28 Aug 2020 16:37:05

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:38:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-28T12:36:55', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '5cdd8fc5-86cc-4a25-b5f1-089f54540e37' User entered 'None (0)'	System	28 Aug 2020 16:37:05
	System	28 Aug 2020 16:37:05

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:38:18

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-28T12:36:58', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '5cdd8fc5-86cc-4a25-b5f1-089f54540e37'	System	28 Aug 2020 16:37:05
User entered 'No (N)'	System	28 Aug 2020 16:37:05

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:38:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-28T12:37:00', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '5cdd8fc5-86cc-4a25-b5f1-089f54540e37' User entered '28 Aug 2020 12:37'	System	28 Aug 2020 16:37:05
	System	28 Aug 2020 16:37:05

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:38:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '28 Aug 2020 12:19'	System	28 Aug 2020 16:02:48

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:38:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '28 Aug 2020 14:49'	System	28 Aug 2020 16:02:48

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
Data entry locked.	System	28 Aug 2020 16:02:48
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 16:02:48

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:38:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-28T21:29:47', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '8baa8ad9-caa5-4cca-a051-70bc76f74bea'	System	29 Aug 2020 01:30:15
User entered 'No interference with activity (1)'	System	29 Aug 2020 01:30:15

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:38:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-28T21:29:50', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '8baa8ad9-caa5-4cca-a051-70bc76f74bea' User entered 'None (0)'	System	29 Aug 2020 01:30:15
	System	29 Aug 2020 01:30:15

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:38:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-28T21:29:53', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '8baa8ad9-caa5-4cca-a051-70bc76f74bea' User entered 'None (0)'	System	29 Aug 2020 01:30:15
	System	29 Aug 2020 01:30:15

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:38:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-28T21:29:55', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '8baa8ad9-caa5-4cca-a051-70bc76f74bea' User entered 'None (0)'	System	29 Aug 2020 01:30:15
	System	29 Aug 2020 01:30:15

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:38:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-28T21:29:58', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '8baa8ad9-caa5-4cca-a051-70bc76f74bea' User entered 'None (0)'	System	29 Aug 2020 01:30:15
	System	29 Aug 2020 01:30:15

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:38:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-28T21:30:00', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '8baa8ad9-caa5-4cca-a051-70bc76f74bea' User entered 'None (0)'	System	29 Aug 2020 01:30:15
	System	29 Aug 2020 01:30:15

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:38:18

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-28T21:30:04', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '8baa8ad9-caa5-4cca-a051-70bc76f74bea' User entered 'No (N)'	System	29 Aug 2020 01:30:15
	System	29 Aug 2020 01:30:15

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:38:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-28T21:30:11', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '8baa8ad9-caa5-4cca-a051-70bc76f74bea' User entered '28 Aug 2020 21:30'	System	29 Aug 2020 01:30:15
	System	29 Aug 2020 01:30:15

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:38:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '28 Aug 2020 15:44'	System	28 Aug 2020 16:02:48

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:38:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 16:02:48

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
Data entry locked.	System	28 Aug 2020 16:02:48
User entered 'Day 2'	System	28 Aug 2020 16:02:48

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:38:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-29T23:57:03', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '44816b85-d216-4d92-9427-bc4d4669e428'	System	30 Aug 2020 03:57:30
User entered 'No interference with activity (1)'	System	30 Aug 2020 03:57:30

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:38:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-29T23:57:06', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '44816b85-d216-4d92-9427-bc4d4669e428' User entered 'None (0)'	System	30 Aug 2020 03:57:30
	System	30 Aug 2020 03:57:30

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:38:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-29T23:57:10', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '44816b85-d216-4d92-9427-bc4d4669e428' User entered 'None (0)'	System	30 Aug 2020 03:57:30
	System	30 Aug 2020 03:57:30

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:38:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-29T23:57:13', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '44816b85-d216-4d92-9427-bc4d4669e428' User entered 'None (0)'	System	30 Aug 2020 03:57:30
	System	30 Aug 2020 03:57:30

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:38:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-29T23:57:16', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '44816b85-d216-4d92-9427-bc4d4669e428' User entered 'None (0)'	System	30 Aug 2020 03:57:30
	System	30 Aug 2020 03:57:30

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:38:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-29T23:57:19', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '44816b85-d216-4d92-9427-bc4d4669e428' User entered 'None (0)'	System	30 Aug 2020 03:57:30
	System	30 Aug 2020 03:57:30

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:38:18

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-29T23:57:22', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '44816b85-d216-4d92-9427-bc4d4669e428' User entered 'No (N)'	System	30 Aug 2020 03:57:30
	System	30 Aug 2020 03:57:30

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:38:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-29T23:57:25', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '44816b85-d216-4d92-9427-bc4d4669e428' User entered '29 Aug 2020 23:57'	System	30 Aug 2020 03:57:30
	System	30 Aug 2020 03:57:30

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:38:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 16:02:48

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:38:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 16:02:48

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
Data entry locked.	System	28 Aug 2020 16:02:48
User entered 'Day 3'	System	28 Aug 2020 16:02:48

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:38:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-30T18:54:53', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'd6f34f1e-d2b2-441a-b11f-48065de141a1'	System	30 Aug 2020 22:55:19
User entered 'No interference with activity (1)'	System	30 Aug 2020 22:55:19

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:38:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-30T18:54:58', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'd6f34f1e-d2b2-441a-b11f-48065de141a1' User entered 'None (0)'	System	30 Aug 2020 22:55:19
	System	30 Aug 2020 22:55:19

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:38:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-30T18:55:00', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'd6f34f1e-d2b2-441a-b11f-48065de141a1' User entered 'None (0)'	System	30 Aug 2020 22:55:19
	System	30 Aug 2020 22:55:19

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:38:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-30T18:55:03', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'd6f34f1e-d2b2-441a-b11f-48065de141a1' User entered 'None (0)'	System	30 Aug 2020 22:55:19
	System	30 Aug 2020 22:55:19

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:38:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-30T18:55:05', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'd6f34f1e-d2b2-441a-b11f-48065de141a1' User entered 'None (0)'	System	30 Aug 2020 22:55:19
	System	30 Aug 2020 22:55:19

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:38:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-30T18:55:08', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'd6f34f1e-d2b2-441a-b11f-48065de141a1' User entered 'None (0)'	System	30 Aug 2020 22:55:19
	System	30 Aug 2020 22:55:19

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:38:18

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-30T18:55:11', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'd6f34f1e-d2b2-441a-b11f-48065de141a1' User entered 'No (N)'	System	30 Aug 2020 22:55:19
	System	30 Aug 2020 22:55:19

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:38:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-30T18:55:15', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'd6f34f1e-d2b2-441a-b11f-48065de141a1' User entered '30 Aug 2020 18:55'	System	30 Aug 2020 22:55:19
	System	30 Aug 2020 22:55:19

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:38:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 16:02:48

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:38:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 16:02:48

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
Data entry locked.	System	28 Aug 2020 16:02:48
User entered 'Day 4'	System	28 Aug 2020 16:02:48

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:38:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-31T23:49:11', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '9d949b7c-d240-4611-88b4-74f8f34a7c54' User entered 'None (0)'	System	01 Sep 2020 03:49:33
	System	01 Sep 2020 03:49:33

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:38:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-31T23:49:14', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '9d949b7c-d240-4611-88b4-74f8f34a7c54' User entered 'None (0)'	System	01 Sep 2020 03:49:33
	System	01 Sep 2020 03:49:33

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:38:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-31T23:49:16', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '9d949b7c-d240-4611-88b4-74f8f34a7c54' User entered 'None (0)'	System	01 Sep 2020 03:49:33
	System	01 Sep 2020 03:49:33

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:38:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-31T23:49:19', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '9d949b7c-d240-4611-88b4-74f8f34a7c54' User entered 'None (0)'	System	01 Sep 2020 03:49:33
	System	01 Sep 2020 03:49:33

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:38:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-31T23:49:22', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '9d949b7c-d240-4611-88b4-74f8f34a7c54' User entered 'None (0)'	System	01 Sep 2020 03:49:33
	System	01 Sep 2020 03:49:33

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:38:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-31T23:49:24', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '9d949b7c-d240-4611-88b4-74f8f34a7c54' User entered 'None (0)'	System	01 Sep 2020 03:49:33
	System	01 Sep 2020 03:49:33

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:38:18

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-31T23:49:27', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '9d949b7c-d240-4611-88b4-74f8f34a7c54'	System	01 Sep 2020 03:49:33
User entered 'No (N)'	System	01 Sep 2020 03:49:33

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:38:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-08-31T23:49:30', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '9d949b7c-d240-4611-88b4-74f8f34a7c54' User entered '31 Aug 2020 23:49'	System	01 Sep 2020 03:49:33
	System	01 Sep 2020 03:49:33

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:38:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 16:02:48

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:38:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 16:02:48

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
Data entry locked.	System	28 Aug 2020 16:02:48
User entered 'Day 5'	System	28 Aug 2020 16:02:48

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:38:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-09-02T04:06:52', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'e08d8019-3ec3-45f7-a9c2-335a04ef53bf' User entered 'None (0)'	System	02 Sep 2020 08:07:12
	System	02 Sep 2020 08:07:12

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:38:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-09-02T04:06:54', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'e08d8019-3ec3-45f7-a9c2-335a04ef53bf' User entered 'None (0)'	System	02 Sep 2020 08:07:12
	System	02 Sep 2020 08:07:12

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:38:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-09-02T04:06:56', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'e08d8019-3ec3-45f7-a9c2-335a04ef53bf' User entered 'None (0)'	System	02 Sep 2020 08:07:12
	System	02 Sep 2020 08:07:12

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:38:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-09-02T04:06:58', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'e08d8019-3ec3-45f7-a9c2-335a04ef53bf' User entered 'None (0)'	System	02 Sep 2020 08:07:12
	System	02 Sep 2020 08:07:12

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:38:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-09-02T04:07:00', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'e08d8019-3ec3-45f7-a9c2-335a04ef53bf' User entered 'None (0)'	System	02 Sep 2020 08:07:12
	System	02 Sep 2020 08:07:12

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:38:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-09-02T04:07:02', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'e08d8019-3ec3-45f7-a9c2-335a04ef53bf' User entered 'None (0)'	System	02 Sep 2020 08:07:12
	System	02 Sep 2020 08:07:12

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:38:18

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-09-02T04:07:05', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'e08d8019-3ec3-45f7-a9c2-335a04ef53bf' User entered 'No (N)'	System	02 Sep 2020 08:07:12
	System	02 Sep 2020 08:07:12

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:38:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-09-02T04:07:07', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'e08d8019-3ec3-45f7-a9c2-335a04ef53bf' User entered '02 Sep 2020 04:07'	System	02 Sep 2020 08:07:12
	System	02 Sep 2020 08:07:12

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:38:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 16:02:48

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:38:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 16:02:48

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
Data entry locked.	System	28 Aug 2020 16:02:48
User entered 'Day 6'	System	28 Aug 2020 16:02:48

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:38:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-09-03T00:06:23', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '3c476d8c-67f9-4d9b-a7b9-2ef762683418' User entered 'None (0)'	System	03 Sep 2020 04:06:42
	System	03 Sep 2020 04:06:42

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:38:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-09-03T00:06:25', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '3c476d8c-67f9-4d9b-a7b9-2ef762683418' User entered 'None (0)'	System	03 Sep 2020 04:06:42
	System	03 Sep 2020 04:06:42

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:38:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-09-03T00:06:27', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '3c476d8c-67f9-4d9b-a7b9-2ef762683418' User entered 'None (0)'	System	03 Sep 2020 04:06:42
	System	03 Sep 2020 04:06:42

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:38:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-09-03T00:06:29', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '3c476d8c-67f9-4d9b-a7b9-2ef762683418' User entered 'None (0)'	System	03 Sep 2020 04:06:42
	System	03 Sep 2020 04:06:42

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:38:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-09-03T00:06:32', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '3c476d8c-67f9-4d9b-a7b9-2ef762683418' User entered 'None (0)'	System	03 Sep 2020 04:06:42
	System	03 Sep 2020 04:06:42

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:38:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-09-03T00:06:34', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '3c476d8c-67f9-4d9b-a7b9-2ef762683418' User entered 'None (0)'	System	03 Sep 2020 04:06:42
	System	03 Sep 2020 04:06:42

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:38:18

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-09-03T00:06:36', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '3c476d8c-67f9-4d9b-a7b9-2ef762683418' User entered 'No (N)'	System	03 Sep 2020 04:06:42
	System	03 Sep 2020 04:06:42

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:38:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-09-03T00:06:39', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '3c476d8c-67f9-4d9b-a7b9-2ef762683418' User entered '03 Sep 2020 00:06'	System	03 Sep 2020 04:06:42
	System	03 Sep 2020 04:06:42

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:38:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 16:02:48

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:38:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 16:02:48

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
Data entry locked.	System	28 Aug 2020 16:02:48
User entered 'Day 7'	System	28 Aug 2020 16:02:48

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:38:18

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-09-03T16:05:36', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '209fe3cd-4023-4e78-948d-35229d86642f' User entered 'None (0)'	System	03 Sep 2020 20:05:53
	System	03 Sep 2020 20:05:53

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:38:18

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-09-03T16:05:38', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '209fe3cd-4023-4e78-948d-35229d86642f' User entered 'None (0)'	System	03 Sep 2020 20:05:53
	System	03 Sep 2020 20:05:53

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:38:18

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-09-03T16:05:39', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '209fe3cd-4023-4e78-948d-35229d86642f' User entered 'None (0)'	System	03 Sep 2020 20:05:53
	System	03 Sep 2020 20:05:53

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:38:18

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-09-03T16:05:42', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '209fe3cd-4023-4e78-948d-35229d86642f' User entered 'None (0)'	System	03 Sep 2020 20:05:53
	System	03 Sep 2020 20:05:53

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:38:18

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-09-03T16:05:44', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '209fe3cd-4023-4e78-948d-35229d86642f' User entered 'None (0)'	System	03 Sep 2020 20:05:53
	System	03 Sep 2020 20:05:53

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:38:18

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-09-03T16:05:46', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '209fe3cd-4023-4e78-948d-35229d86642f' User entered 'None (0)'	System	03 Sep 2020 20:05:53
	System	03 Sep 2020 20:05:53

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:38:18

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-09-03T16:05:48', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '209fe3cd-4023-4e78-948d-35229d86642f' User entered 'No (N)'	System	03 Sep 2020 20:05:53
	System	03 Sep 2020 20:05:53

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:38:18

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-09-03T16:05:50', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '209fe3cd-4023-4e78-948d-35229d86642f' User entered '03 Sep 2020 16:05'	System	03 Sep 2020 20:05:53
	System	03 Sep 2020 20:05:53

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:38:18

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 16:02:48

US3182065

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:38:18

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 16:02:48

US3182065

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	19 Feb 2021 17:59:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:28:28
User entered 'Yes (Y)'	Alec Ireland (b) (4) (b) (4)	04 Sep 2020 18:03:57

US3182065

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:18

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	19 Feb 2021 17:59:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:28:28
User entered '4 Sep 2020'	Alec Ireland (b) (4) (b) (4)	04 Sep 2020 18:03:57

US3182065

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	19 Feb 2021 17:59:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:28:28
User entered 'Contact Made (CONTACT MADE)'	Alec Ireland (b) (4) (b) (4)	04 Sep 2020 18:03:57

US3182065

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	19 Feb 2021 17:59:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:28:28
User entered empty.	Alec Ireland (b) (4) (b) (4)	04 Sep 2020 18:03:57

US3182065

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:38:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	19 Feb 2021 17:59:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:28:33
User entered 'Yes (Y)'	Alec Ireland (b) (4) (b) (4)	04 Sep 2020 18:03:51

US3182065

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:38:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User entered '1'	System	04 Sep 2020 18:03:51

US3182065

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:32:28
User entered 'Yes (Y)'	Alec Ireland (b) (4) (b) (4)	15 Sep 2020 18:43:44

US3182065

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:18

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:32:28
User entered '11 Sep 2020'	Alec Ireland (b) (4) (b) (4)	15 Sep 2020 18:43:44

US3182065

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:32:28
User entered 'Contact Made (CONTACT MADE)'	Alec Ireland (b) (4) (b) (4)	15 Sep 2020 18:43:44

US3182065

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:32:28
User entered empty.	Alec Ireland (b) (4) (b) (4)	15 Sep 2020 18:43:44

US3182065

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:38:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:32:33
User entered 'Yes (Y)'	Alec Ireland (b) (4) (b) (4)	15 Sep 2020 18:43:49

US3182065

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:38:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User entered 'I'	System	15 Sep 2020 18:43:49

US3182065

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:32:51
User entered 'Yes (Y)'	Alec Ireland (b) (4) (b) (4)	23 Sep 2020 16:20:49

US3182065

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:18

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:32:51
User entered '18 Sep 2020'	Alec Ireland (b) (4) (b) (4)	23 Sep 2020 16:20:49

US3182065

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:32:51
User entered 'Contact Made (CONTACT MADE)'	Alec Ireland (b) (4) (b) (4)	23 Sep 2020 16:20:49

US3182065

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:32:51
User entered empty.	Alec Ireland (b) (4) (b) (4)	23 Sep 2020 16:20:49

US3182065

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:38:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:32:57
User entered 'Yes (Y)'	Alec Ireland (b) (4) (b) (4)	23 Sep 2020 16:20:54

US3182065

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:38:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User entered 'I'	System	23 Sep 2020 16:20:54

US3182065

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:38:18

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:35:52
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	25 Sep 2020 16:49:11

US3182065

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:38:18

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:35:52
User entered '23 Sep 2020'	Cassie Uminski (b) (4) (b) (4)	25 Sep 2020 16:49:11

US3182065

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:38:18

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:35:52
User entered 'Clinic (Clinic)'	Cassie Uminski (b) (4) (b) (4)	25 Sep 2020 16:49:11

US3182065

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:38:18

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User entered 'VISIT3'	System	25 Sep 2020 16:49:11

US3182065

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:36:15
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	25 Sep 2020 16:49:33

US3182065

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:36:15
User entered '23 Sep 2020'	Cassie Uminski (b) (4) (b) (4)	25 Sep 2020 16:49:33

US3182065

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:18

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:36:15
User entered '11:05'	Cassie Uminski (b) (4) (b) (4)	25 Sep 2020 16:49:33

US3182065

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:18

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User entered '23 Sep 2020 11:05'	System	25 Sep 2020 16:49:33

US3182065

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:36:15
User entered '98.5' F	Cassie Uminski (b) (4) (b) (4)	25 Sep 2020 16:49:33

US3182065

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:36:15
User entered 'Oral (Oral)'	Cassie Uminski (b) (4) (b) (4)	25 Sep 2020 16:49:33

US3182065

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:36:15
User entered empty.	Cassie Uminski (b) (4) (b) (4)	25 Sep 2020 16:49:33

US3182065

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:36:15
User entered '83'	Cassie Uminski (b) (4) (b) (4)	25 Sep 2020 16:49:33

US3182065

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User entered 'bpm'	System	25 Sep 2020 16:49:33

US3182065

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:18

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:36:15
User entered '16'	Cassie Uminski (b) (4) (b) (4)	25 Sep 2020 16:49:33

US3182065

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User entered 'breaths/min'	System	25 Sep 2020 16:49:33

US3182065

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:18

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:36:15
User entered '129'	Cassie Uminski (b) (4) (b) (4)	25 Sep 2020 16:49:33

US3182065

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User entered 'mmHg'	System	25 Sep 2020 16:49:33

US3182065

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:36:15
User entered '84'	Cassie Uminski (b) (4) (b) (4)	25 Sep 2020 16:49:33

US3182065

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:18

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User entered 'mmHg'	System	25 Sep 2020 16:49:33

US3182065

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:18

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19

US3182065

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:18

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19

US3182065

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:38:18

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:36:25
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	25 Sep 2020 16:49:45

US3182065

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:38:18

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:36:25
User entered empty.	Cassie Uminski (b) (4) (b) (4)	25 Sep 2020 16:49:45

US3182065

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:38:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:36:32
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	25 Sep 2020 16:49:54

US3182065

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:38:18

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:36:32
User entered '23 Sep 2020'	Cassie Uminski (b) (4) (b) (4)	25 Sep 2020 16:49:54

US3182065

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:38:18

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:36:32
User entered '11:08'	Cassie Uminski (b) (4) (b) (4)	25 Sep 2020 16:49:54

US3182065

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:38:18

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User entered '23 Sep 2020 11:08'	System	25 Sep 2020 16:49:54

US3182065

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:38:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	15 Feb 2021 19:05:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 19:33:52
User closed query 'Why are they not continuing? Should this be yes? ' (Site from CRA).		22 Oct 2020 19:33:36
Query 'Why are they not continuing? Should this be yes? ' answered with 'Updated' (Site from CRA).	Cassie Uminski (b) (4)	22 Oct 2020 17:39:05
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Cassie Uminski (b) (4)	22 Oct 2020 17:39:00
User opened query 'Why are they not continuing? Should this be yes? ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:37:19
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	25 Sep 2020 16:49:58

US3182065

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:38:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User entered '1'	System	22 Oct 2020 17:39:00
User entered empty.	System	25 Sep 2020 16:49:58

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46
Data entry locked.	System	31 Jul 2020 21:28:45
User entered 'Day 64'	System	31 Jul 2020 21:28:45

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Please 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)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Please 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)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Please 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)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46
Data entry locked.	System	31 Jul 2020 21:28:45
User entered '28 Sep 2020 00:01'	System	31 Jul 2020 21:28:45

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46
Data entry locked.	System	31 Jul 2020 21:28:45
User entered '02 Oct 2020 23:59'	System	31 Jul 2020 21:28:45

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46
Data entry locked.	System	31 Jul 2020 21:28:45
User entered 'Day 71'	System	31 Jul 2020 21:28:45

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Please 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)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Please 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)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Please 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)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46
Data entry locked.	System	31 Jul 2020 21:28:45
User entered '05 Oct 2020 00:01'	System	31 Jul 2020 21:28:45

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46
Data entry locked.	System	31 Jul 2020 21:28:45
User entered '09 Oct 2020 23:59'	System	31 Jul 2020 21:28:45

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46
Data entry locked.	System	31 Jul 2020 21:28:45
User entered 'Day 78'	System	31 Jul 2020 21:28:45

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46

US3182065

Folder: Safety Follow Up Diary (1)

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[Please 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)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Please 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)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Please 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)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46

US3182065

Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46
Data entry locked.	System	31 Jul 2020 21:28:45
User entered '12 Oct 2020 00:01'	System	31 Jul 2020 21:28:45

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:14:46
Data entry locked.	System	31 Jul 2020 21:28:45
User entered '16 Oct 2020 23:59'	System	31 Jul 2020 21:28:45

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
Data entry locked.	System	31 Jul 2020 21:28:45
User entered 'Day 92'	System	31 Jul 2020 21:28:45

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-10-26T00:01:30', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'be1933c2-f7d2-4c08-9f79-c15e3b297055'	System	26 Oct 2020 04:02:27
User entered 'No (N)'	System	26 Oct 2020 04:02:27

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-10-26T00:01:59', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'be1933c2-f7d2-4c08-9f79-c15e3b297055'	System	26 Oct 2020 04:02:27
User entered 'Yes (Y)'	System	26 Oct 2020 04:02:27

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Please 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)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-10-26T00:02:03', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'be1933c2-f7d2-4c08-9f79-c15e3b297055'	System	26 Oct 2020 04:02:27
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	26 Oct 2020 04:02:27

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-10-26T00:02:17', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'be1933c2-f7d2-4c08-9f79-c15e3b297055' User entered '26 Oct 2020 00:02:17'	System	26 Oct 2020 04:02:27
	System	26 Oct 2020 04:02:27

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
Data entry locked.	System	31 Jul 2020 21:28:45
User entered '26 Oct 2020 00:01'	System	31 Jul 2020 21:28:45

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
Data entry locked.	System	31 Jul 2020 21:28:45
User entered '30 Oct 2020 23:59'	System	31 Jul 2020 21:28:45

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
Data entry locked.	System	31 Jul 2020 21:28:45
User entered 'Day 99'	System	31 Jul 2020 21:28:45

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-11-03T02:46:49', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'fe4e1cc5-0032-46b9-b1d2-e4f8d67dc009' User entered 'No (N)'	System	03 Nov 2020 07:47:27
	System	03 Nov 2020 07:47:27

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-11-03T02:46:58', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'fe4e1cc5-0032-46b9-b1d2-e4f8d67dc009'	System	03 Nov 2020 07:47:27
User entered 'Yes (Y)'	System	03 Nov 2020 07:47:27

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Please 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)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-11-03T02:47:08', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'fe4e1cc5-0032-46b9-b1d2-e4f8d67dc009'	System	03 Nov 2020 07:47:27
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	03 Nov 2020 07:47:27

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-11-03T02:47:16', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'fe4e1cc5-0032-46b9-b1d2-e4f8d67dc009' User entered '03 Nov 2020 02:47:16'	System	03 Nov 2020 07:47:27
	System	03 Nov 2020 07:47:27

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
Data entry locked.	System	31 Jul 2020 21:28:45
User entered '02 Nov 2020 00:01'	System	31 Jul 2020 21:28:45

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
Data entry locked.	System	31 Jul 2020 21:28:45
User entered '06 Nov 2020 23:59'	System	31 Jul 2020 21:28:45

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
Data entry locked.	System	31 Jul 2020 21:28:45
User entered 'Day 106'	System	31 Jul 2020 21:28:45

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-11-11T10:23:05', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '5837e9d2-09f1-4d2f-9bf5-a46975568a21' User entered 'No (N)'	System	11 Nov 2020 15:23:24
	System	11 Nov 2020 15:23:24

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-11-11T10:23:15', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '5837e9d2-09f1-4d2f-9bf5-a46975568a21' User entered 'No (N)'	System	11 Nov 2020 15:23:24
	System	11 Nov 2020 15:23:24

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-11-11T10:23:20', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '5837e9d2-09f1-4d2f-9bf5-a46975568a21' User entered '11 Nov 2020 10:23:20'	System	11 Nov 2020 15:23:24
	System	11 Nov 2020 15:23:24

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
Data entry locked.	System	31 Jul 2020 21:28:45
User entered '09 Nov 2020 00:01'	System	31 Jul 2020 21:28:45

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
Data entry locked.	System	31 Jul 2020 21:28:45
User entered '13 Nov 2020 23:59'	System	31 Jul 2020 21:28:45

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
Data entry locked.	System	31 Jul 2020 21:28:45
User entered 'Day 113'	System	31 Jul 2020 21:28:45

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
User closed query 'Per DM CLR: 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).		15 Feb 2021 16:52:55
Query 'Per DM CLR: 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 'This was marked in error by subject' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	10 Feb 2021 19:30:02
User opened query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 17:18:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-11-17T04:17:18', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '4a18caa8-f614-4f8e-9e24-38ac11cbc3dc'	System	17 Nov 2020 09:17:57
User entered 'Yes (Y)'	System	17 Nov 2020 09:17:57

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-11-17T04:17:23', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '4a18caa8-f614-4f8e-9e24-38ac11cbc3dc'	System	17 Nov 2020 09:17:57
User entered 'No (N)'	System	17 Nov 2020 09:17:57

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-11-17T04:17:31', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '4a18caa8-f614-4f8e-9e24-38ac11cbc3dc' User entered 'No (N)'	System	17 Nov 2020 09:17:57
	System	17 Nov 2020 09:17:57

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-11-17T04:17:39', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '4a18caa8-f614-4f8e-9e24-38ac11cbc3dc'	System	17 Nov 2020 09:17:57
User entered 'Yes (Y)'	System	17 Nov 2020 09:17:57

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Please 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)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-11-17T04:17:43', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '4a18caa8-f614-4f8e-9e24-38ac11cbc3dc'	System	17 Nov 2020 09:17:57
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	17 Nov 2020 09:17:57

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-11-17T04:17:47', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '4a18caa8-f614-4f8e-9e24-38ac11cbc3dc' User entered '17 Nov 2020 04:17:47'	System	17 Nov 2020 09:17:57
	System	17 Nov 2020 09:17:57

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
Data entry locked.	System	31 Jul 2020 21:28:45
User entered '16 Nov 2020 00:01'	System	31 Jul 2020 21:28:45

US3182065

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:55:38
Data entry locked.	System	31 Jul 2020 21:28:45
User entered '20 Nov 2020 23:59'	System	31 Jul 2020 21:28:45

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[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 (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-11-23T11:42:03', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'b85374eb-fc17-4394-841e-f94d1606d0ec' User entered 'No (N)'	System	23 Nov 2020 16:42:17
	System	23 Nov 2020 16:42:17

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

Have you been exposed to someone with 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 (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-11-23T11:42:09', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'b85374eb-fc17-4394-841e-f94d1606d0ec' User entered 'No (N)'	System	23 Nov 2020 16:42:17

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-11-23T11:42:14', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'b85374eb-fc17-4394-841e-f94d1606d0ec' User entered '23 Nov 2020 11:42:14'	System	23 Nov 2020 16:42:17
	System	23 Nov 2020 16:42:17

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[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 (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-12-01T07:05:54', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'd3643724-2c6b-4bb8-9786-c9a1a77a6a6c' User entered 'No (N)'	System	01 Dec 2020 12:06:05
	System	01 Dec 2020 12:06:05

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

Have you been exposed to someone with 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 (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-12-01T07:05:58', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'd3643724-2c6b-4bb8-9786-c9a1a77a6a6c' User entered 'No (N)'	System	01 Dec 2020 12:06:05
	System	01 Dec 2020 12:06:05

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-12-01T07:06:01', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'd3643724-2c6b-4bb8-9786-c9a1a77a6a6c' User entered '01 Dec 2020 07:06:01'	System	01 Dec 2020 12:06:05
	System	01 Dec 2020 12:06:05

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[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 (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-12-04T03:34:28', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'ac47b159-2254-4031-b120-fcbeeb0d6b7c' User entered 'No (N)'	System	04 Dec 2020 08:34:38
	System	04 Dec 2020 08:34:38

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Have you been exposed to someone with 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 (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-12-04T03:34:32', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'ac47b159-2254-4031-b120-fcbeeb0d6b7c' User entered 'No (N)'	System	04 Dec 2020 08:34:38
	System	04 Dec 2020 08:34:38

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-12-04T03:34:35', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'ac47b159-2254-4031-b120-fcbeeb0d6b7c' User entered '04 Dec 2020 03:34:35'	System	04 Dec 2020 08:34:38
	System	04 Dec 2020 08:34:38

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[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 (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-12-15T06:57:47', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '1aee235f-b430-4807-b885-ae0a5cc3ca0a' User entered 'No (N)'	System	15 Dec 2020 11:57:57
	System	15 Dec 2020 11:57:57

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

Have you been exposed to someone with 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 (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-12-15T06:57:50', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '1aee235f-b430-4807-b885-ae0a5cc3ca0a' User entered 'No (N)'	System	15 Dec 2020 11:57:57
	System	15 Dec 2020 11:57:57

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-12-15T06:57:54', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '1aee235f-b430-4807-b885-ae0a5cc3ca0a' User entered '15 Dec 2020 06:57:54'	System	15 Dec 2020 11:57:57
	System	15 Dec 2020 11:57:57

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[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 (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-12-20T10:03:05', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '268b8d64-8ff7-482f-9a71-6ef8183a62a8' User entered 'No (N)'	System	20 Dec 2020 15:03:15
	System	20 Dec 2020 15:03:15

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

Have you been exposed to someone with 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 (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-12-20T10:03:08', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '268b8d64-8ff7-482f-9a71-6ef8183a62a8' User entered 'No (N)'	System	20 Dec 2020 15:03:15
	System	20 Dec 2020 15:03:15

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-12-20T10:03:12', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '268b8d64-8ff7-482f-9a71-6ef8183a62a8' User entered '20 Dec 2020 10:03:12'	System	20 Dec 2020 15:03:15
	System	20 Dec 2020 15:03:15

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[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 (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-12-26T20:04:18', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '3592d75f-3051-40dd-8a3f-a374283762dc' User entered 'No (N)'	System	27 Dec 2020 01:04:29
	System	27 Dec 2020 01:04:29

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Have you been exposed to someone with 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 (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-12-26T20:04:20', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '3592d75f-3051-40dd-8a3f-a374283762dc' User entered 'No (N)'	System	27 Dec 2020 01:04:29
	System	27 Dec 2020 01:04:29

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2020-12-26T20:04:25', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '3592d75f-3051-40dd-8a3f-a374283762dc' User entered '26 Dec 2020 20:04:25'	System	27 Dec 2020 01:04:29
	System	27 Dec 2020 01:04:29

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[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 (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2021-01-04T16:03:01', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'bd9903aa-9979-4b1c-bdd6-4a5f8d073298' User entered 'No (N)'	System	04 Jan 2021 21:03:12
	System	04 Jan 2021 21:03:12

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

Have you been exposed to someone with 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 (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2021-01-04T16:03:05', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'bd9903aa-9979-4b1c-bdd6-4a5f8d073298'	System	04 Jan 2021 21:03:12
User entered 'No (N)'	System	04 Jan 2021 21:03:12

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2021-01-04T16:03:08', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'bd9903aa-9979-4b1c-bdd6-4a5f8d073298' User entered '04 Jan 2021 16:03:08'	System	04 Jan 2021 21:03:12
	System	04 Jan 2021 21:03:12

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[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 (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2021-01-15T22:36:49', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'a5589bf8-72aa-44a7-9314-87c8330bcc74' User entered 'No (N)'	System	16 Jan 2021 03:36:59
	System	16 Jan 2021 03:36:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

Have you been exposed to someone with 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 (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2021-01-15T22:36:52', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'a5589bf8-72aa-44a7-9314-87c8330bcc74' User entered 'No (N)'	System	16 Jan 2021 03:36:59
	System	16 Jan 2021 03:36:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2021-01-15T22:36:55', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'a5589bf8-72aa-44a7-9314-87c8330bcc74' User entered '15 Jan 2021 22:36:55'	System	16 Jan 2021 03:36:59
	System	16 Jan 2021 03:36:59

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[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 (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2021-01-22T06:53:51', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '07006b83-fa55-4f6d-bcbe-8c76e489a62e' User entered 'No (N)'	System	22 Jan 2021 11:54:02
	System	22 Jan 2021 11:54:02

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

Have you been exposed to someone with 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 (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2021-01-22T06:53:55', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '07006b83-fa55-4f6d-bcbe-8c76e489a62e' User entered 'No (N)'	System	22 Jan 2021 11:54:02

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2021-01-22T06:54:00', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '07006b83-fa55-4f6d-bcbe-8c76e489a62e' User entered '22 Jan 2021 06:54:00'	System	22 Jan 2021 11:54:02
	System	22 Jan 2021 11:54:02

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[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 (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2021-02-08T08:47:15', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '4e499a62-65f7-4540-b435-3291418129c7' User entered 'Yes (Y)'	System	08 Feb 2021 13:47:40
	System	08 Feb 2021 13:47:40

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Have you been exposed to someone with 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 (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2021-02-08T08:47:19', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '4e499a62-65f7-4540-b435-3291418129c7'	System	08 Feb 2021 13:47:40
User entered 'No (N)'	System	08 Feb 2021 13:47:40

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[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 (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2021-02-08T08:47:25', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '4e499a62-65f7-4540-b435-3291418129c7'	System	08 Feb 2021 13:47:40
User entered 'No (N)'	System	08 Feb 2021 13:47:40

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[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 (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2021-02-08T08:47:30', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '4e499a62-65f7-4540-b435-3291418129c7'	System	08 Feb 2021 13:47:40
User entered 'No (N)'	System	08 Feb 2021 13:47:40

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2021-02-08T08:47:37', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '4e499a62-65f7-4540-b435-3291418129c7' User entered '08 Feb 2021 08:47:37'	System	08 Feb 2021 13:47:40
	System	08 Feb 2021 13:47:40

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[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 (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2021-02-28T13:32:37-05:00', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '2803b54b-ff8b-487a-864d-636b664a273a' User entered 'No (N)'	System	28 Feb 2021 18:32:48
	System	28 Feb 2021 18:32:48

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

Have you been exposed to someone with 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 (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2021-02-28T13:32:41-05:00', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '2803b54b-ff8b-487a-864d-636b664a273a' User entered 'No (N)'	System	28 Feb 2021 18:32:48
	System	28 Feb 2021 18:32:48

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2021-02-28T13:32:44-05:00', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '2803b54b-ff8b-487a-864d-636b664a273a' User entered '28 Feb 2021 18:32:44'	System	28 Feb 2021 18:32:48
	System	28 Feb 2021 18:32:48

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[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 (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2021-03-05T02:34:19-05:00', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '966cf193-44d2-47eb-b586-5440299578d6'	System	05 Mar 2021 07:34:30
User entered 'No (N)'	System	05 Mar 2021 07:34:30

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

Have you been exposed to someone with 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 (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2021-03-05T02:34:21-05:00', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '966cf193-44d2-47eb-b586-5440299578d6'	System	05 Mar 2021 07:34:30
User entered 'No (N)'	System	05 Mar 2021 07:34:30

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2021-03-05T02:34:25-05:00', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '966cf193-44d2-47eb-b586-5440299578d6'	System	05 Mar 2021 07:34:30
User entered '05 Mar 2021 02:34:25'	System	05 Mar 2021 07:34:30

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[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 (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2021-03-29T10:16:23-04:00', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'e24dab3e-617c-48cf-8c66-ac30e445c371' User entered 'No (N)'	System	29 Mar 2021 14:16:34
	System	29 Mar 2021 14:16:34

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

Have you been exposed to someone with 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 (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2021-03-29T10:16:25-04:00', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'e24dab3e-617c-48cf-8c66-ac30e445c371'	System	29 Mar 2021 14:16:34
User entered 'No (N)'	System	29 Mar 2021 14:16:34

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2021-03-29T10:16:28-04:00', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: 'e24dab3e-617c-48cf-8c66-ac30e445c371' User entered '29 Mar 2021 10:16:28'	System	29 Mar 2021 14:16:34
	System	29 Mar 2021 14:16:34

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[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 (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2021-04-06T16:01:03-04:00', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '53b1a661-20cb-4ce6-a5b7-8f8d9a5ae5f0'	System	06 Apr 2021 20:01:13
User entered 'No (N)'	System	06 Apr 2021 20:01:13

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

Have you been exposed to someone with 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 (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2021-04-06T16:01:04-04:00', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '53b1a661-20cb-4ce6-a5b7-8f8d9a5ae5f0' User entered 'No (N)'	System	06 Apr 2021 20:01:13
	System	06 Apr 2021 20:01:13

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2021-04-06T16:01:08-04:00', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '53b1a661-20cb-4ce6-a5b7-8f8d9a5ae5f0'	System	06 Apr 2021 20:01:13
User entered '06 Apr 2021 16:01:08'	System	06 Apr 2021 20:01:13

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[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 (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2021-04-11T13:57:37-04:00', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '28d4efd4-02fb-4eff-bbd3-ced11209b9ca'	System	11 Apr 2021 17:57:45
User entered 'No (N)'	System	11 Apr 2021 17:57:45

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

Have you been exposed to someone with 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 (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2021-04-11T13:57:39-04:00', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '28d4efd4-02fb-4eff-bbd3-ced11209b9ca'	System	11 Apr 2021 17:57:45
User entered 'No (N)'	System	11 Apr 2021 17:57:45

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2021-04-11T13:57:43-04:00', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '28d4efd4-02fb-4eff-bbd3-ced11209b9ca' User entered '11 Apr 2021 13:57:43'	System	11 Apr 2021 17:57:45
	System	11 Apr 2021 17:57:45

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 10:14:46

US3182065

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:38:18

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:14:46
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 10:14:46

US3182065

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:38:18

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)	24 Apr 2021 12:50:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2021-02-28T13:32:50-05:00', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '71b8bfdc-f897-4bdd-b49e-b0d840bdcfc2'	System	28 Feb 2021 18:33:07
User entered 'Yes (Y)'	System	28 Feb 2021 18:33:07

US3182065

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:38:18

Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2021-02-28T13:32:54-05:00', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '71b8bfdc-f897-4bdd-b49e-b0d840bdcfc2'	System	28 Feb 2021 18:33:07
User entered 'No (N)'	System	28 Feb 2021 18:33:07

US3182065

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:38:18

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:50:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (742722EF-88F3-4933-9E90-DB46E2CA6B5A)', Time: '2021-02-28T13:32:57-05:00', User OID: 'PatientReportedOutcome (US3182065)', ODM File OID: '71b8bfdc-f897-4bdd-b49e-b0d840bdcfc2'	System	28 Feb 2021 18:33:07
User entered '28 Feb 2021 18:32:57'	System	28 Feb 2021 18:33:07

US3182065

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:20:51
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	22 Oct 2020 17:39:22

US3182065

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:18

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:20:51
User entered '22 Oct 2020'	Cassie Uminski (b) (4) (b) (4)	22 Oct 2020 17:39:22

US3182065

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:20:51
User entered 'Contact Made (CONTACT MADE)'	Cassie Uminski (b) (4) (b) (4)	22 Oct 2020 17:39:22

US3182065

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:20:51
User entered empty.	Cassie Uminski (b) (4) (b) (4)	22 Oct 2020 17:39:22

US3182065

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:38:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:20:57
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	22 Oct 2020 17:40:01

US3182065

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:38:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 22:29:19
User entered 'I'	System	22 Oct 2020 17:40:01

US3182065

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:38:00
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 14:51:53
User entered 'Yes (Y)'	Gabby Jacobs (b) (4) (b) (4)	30 Dec 2020 16:08:57

US3182065

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:18

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:38:00
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 14:51:53
User closed query 'Safety Call Day 119 'Date of Contact or Contact Attempt' is less than 76 days or greater than 104 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).		01 Jan 2021 15:37:48
User entered '19 Nov 2020' reason for change: Data Entry Error	Cassie Uminski (b) (4) (b) (4)	30 Dec 2020 16:25:53
Query 'Safety Call Day 119 'Date of Contact or Contact Attempt' is less than 76 days or greater than 104 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered with 'updated ' (Site from System).	Gabby Jacobs (b) (4) (b) (4)	30 Dec 2020 16:09:06
User opened query 'Safety Call Day 119 'Date of Contact or Contact Attempt' is less than 76 days or greater than 104 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	30 Dec 2020 16:08:57
User entered '19 Dec 2020'	Gabby Jacobs (b) (4) (b) (4)	30 Dec 2020 16:08:57

US3182065

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:38:00
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 14:51:53
User entered 'Contact Made (CONTACT MADE)'	Gabby Jacobs (b) (4) (b) (4)	30 Dec 2020 16:08:57

US3182065

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:38:00
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 14:51:53
User entered empty.	Gabby Jacobs (b) (4) (b) (4)	30 Dec 2020 16:08:57

US3182065

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:38:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:38:00
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 14:52:33
User entered 'Yes (Y)'	Gabby Jacobs (b) (4) (b) (4)	30 Dec 2020 16:16:32

US3182065

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:38:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:38:00
User entered 'I'	System	30 Dec 2020 16:16:32

US3182065

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:38:00
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 14:52:40
User entered 'Yes (Y)'	Gabby Jacobs (b) (4) (b) (4)	30 Dec 2020 16:21:58

US3182065

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:18

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:38:00
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
User closed query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 14JAN2021 under Participant Decision Visit / OL-D1 in PPD central lab, however same is missing in EDC. Please reconcile the data and update as appropriate. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Feb 2021 07:35:44
Query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 14JAN2021 under Participant Decision Visit / OL-D1 in PPD central lab, however same is missing in EDC. Please reconcile the data and update as appropriate. Else clarify, thank you.' answered with 'Updated' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	10 Feb 2021 19:27:43
User opened query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 14JAN2021 under Participant Decision Visit / OL-D1 in PPD central lab, however same is missing in EDC. Please reconcile the data and update as appropriate. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 10:08:57
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 14:52:40
User entered '26 Dec 2020'	Gabby Jacobs (b) (4) (b) (4)	30 Dec 2020 16:21:58

US3182065

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:38:00
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 14:52:40
User entered 'Contact Made (CONTACT MADE)'	Gabby Jacobs (b) (4) (b) (4)	30 Dec 2020 16:21:58

US3182065

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:38:00
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 14:52:40
User entered empty.	Gabby Jacobs (b) (4) (b) (4)	30 Dec 2020 16:21:58

US3182065

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:38:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:38:00
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 14:52:44
User entered 'Yes (Y)'	Gabby Jacobs (b) (4) (b) (4)	30 Dec 2020 16:22:54

US3182065

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:38:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:38:00
User entered 'I'	System	30 Dec 2020 16:22:54

US3182065

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:38:00
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:17:11
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	08 Feb 2021 19:26:44

US3182065

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:18

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:38:00
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:17:11
User entered '25 Jan 2021'	Cassie Uminski (b) (4) (b) (4)	08 Feb 2021 19:26:44

US3182065

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:38:00
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:17:11
User entered 'Contact Made (CONTACT MADE)'	Cassie Uminski (b) (4) (b) (4)	08 Feb 2021 19:26:44

US3182065

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:38:00
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:17:11
User entered empty.	Cassie Uminski (b) (4) (b) (4)	08 Feb 2021 19:26:44

US3182065

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:38:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:38:00
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:17:15
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	08 Feb 2021 19:35:51

US3182065

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:38:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:38:00
User entered 'I'	System	08 Feb 2021 19:35:51

US3182065

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:38:18

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:38:00
User closed query '?????????Per CDM: Visit 4 Day and OL-D29 are both dated 24FEB2021 however, the data on the Physical Examination forms in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile.' (Site from DM).		02 Apr 2021 07:55:19
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:51:12
Query '?????????Per CDM: Visit 4 Day 209 and OL-D29 are both dated 24FEB2021 however, the data on the Physical Examination forms in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile.' answered with 'Updated' (Site from DM).	Cassie Uminski (b) (4)	31 Mar 2021 13:39:07
User opened query '?????????Per CDM: Visit 4 Day and OL-D29 are both dated 24FEB2021 however, the data on the Physical Examination forms in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 18:20:45
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:44:32
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	10 Mar 2021 16:51:38

US3182065

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:38:18

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:38:00
DataPoint Verified.		01 Apr 2021 13:51:12
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:44:32
User entered '24 Feb 2021'	(b) (4) Cassie Uminski (b) (4) (b) (4)	10 Mar 2021 16:51:38

US3182065

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:38:18

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:38:00
DataPoint Verified.		01 Apr 2021 13:51:12
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:44:32
User entered 'Clinic (Clinic)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	10 Mar 2021 16:51:38

US3182065

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:38:18

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:38:00
User entered 'VISIT4'	System	10 Mar 2021 16:51:38

US3182065

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:38:00
DataPoint Verified.		01 Apr 2021 13:53:08
User signature succeeded.	Mary Beth Manning	31 Mar 2021 14:53:04
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	31 Mar 2021 13:38:28

US3182065

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:38:00
DataPoint Verified.		01 Apr 2021 13:53:08
User signature succeeded.	Mary Beth Manning	31 Mar 2021 14:53:04
User entered '24 Feb 2021'	(b) (4) Cassie Uminski (b) (4) (b) (4)	31 Mar 2021 13:38:28

US3182065

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:18

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:38:00
DataPoint Verified.		01 Apr 2021 13:53:08
User signature succeeded.	Mary Beth Manning	31 Mar 2021 14:53:04
User entered '16:07'	(b) (4) Cassie Uminski (b) (4) (b) (4)	31 Mar 2021 13:38:28

US3182065

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:18

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:38:00
User entered '24 Feb 2021 16:07'	System	31 Mar 2021 13:38:28

US3182065

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:38:00
DataPoint Verified.		01 Apr 2021 13:53:08
User signature succeeded.	Mary Beth Manning	31 Mar 2021 14:53:04
	(b) (4)	
User entered '98.1' F	Cassie Uminski (b) (4)	31 Mar 2021 13:38:28
	(b) (4)	

US3182065

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:38:00
DataPoint Verified.		01 Apr 2021 13:53:08
User signature succeeded.	Mary Beth Manning	31 Mar 2021 14:53:04
User entered 'Oral (Oral)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	31 Mar 2021 13:38:28

US3182065

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:38:00
DataPoint Verified.		01 Apr 2021 13:53:08
User signature succeeded.	Mary Beth Manning	31 Mar 2021 14:53:04
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	31 Mar 2021 13:38:28
	(b) (4)	

US3182065

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:38:00
DataPoint Verified.		01 Apr 2021 13:53:08
User signature succeeded.	Mary Beth Manning	31 Mar 2021 14:53:04
User entered '94'	(b) (4) Cassie Uminski (b) (4) (b) (4)	31 Mar 2021 13:38:28

US3182065

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:38:00
User entered 'bpm'	System	31 Mar 2021 13:38:28

US3182065

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:18

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:38:00
DataPoint Verified.		01 Apr 2021 13:53:08
User signature succeeded.	Mary Beth Manning	31 Mar 2021 14:53:04
User entered '16'	(b) (4) Cassie Uminski (b) (4) (b) (4)	31 Mar 2021 13:38:28

US3182065

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:38:00
User entered 'breaths/min'	System	31 Mar 2021 13:38:28

US3182065

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:38:00
DataPoint Verified.		01 Apr 2021 13:53:08
User signature succeeded.	Mary Beth Manning	31 Mar 2021 14:53:04
User entered '124'	(b) (4) Cassie Uminski (b) (4) (b) (4)	31 Mar 2021 13:38:28

US3182065

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:38:00
User entered 'mmHg'	System	31 Mar 2021 13:38:28

US3182065

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:38:00
DataPoint Verified.		01 Apr 2021 13:53:08
User signature succeeded.	Mary Beth Manning	31 Mar 2021 14:53:04
User entered '81'	(b) (4) Cassie Uminski (b) (4) (b) (4)	31 Mar 2021 13:38:28

US3182065

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:18

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:38:00
User entered 'mmHg'	System	31 Mar 2021 13:38:28

US3182065

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:18

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:38:00

US3182065

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:18

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:38:00

US3182065

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:38:18

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:38:00
DataPoint Verified.		01 Apr 2021 13:53:13
User signature succeeded.	Mary Beth Manning	31 Mar 2021 14:53:04
Signature has been broken.	(b) (4)	
	Cassie Uminski (b) (4)	31 Mar 2021 13:39:24
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Cassie Uminski (b) (4)	31 Mar 2021 13:39:24
	(b) (4)	
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:44:32
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	10 Mar 2021 16:51:47
	(b) (4)	

US3182065

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:38:18

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:38:00
DataPoint Verified.		01 Apr 2021 13:53:13
User signature succeeded.	Mary Beth Manning	31 Mar 2021 14:53:04
	(b) (4)	
Signature has been broken.	Cassie Uminski (b) (4)	31 Mar 2021 13:39:24
	(b) (4)	
User entered '24 Feb 2021' reason for change: Data Entry Error	Cassie Uminski (b) (4)	31 Mar 2021 13:39:24
	(b) (4)	
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:44:32
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	10 Mar 2021 16:51:47
	(b) (4)	

US3182065

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:38:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:38:00
DataPoint Verified.		01 Apr 2021 13:53:23
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:44:32
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	10 Mar 2021 16:52:16

US3182065

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:38:18

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:38:00
DataPoint Verified.		01 Apr 2021 13:53:23
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:44:32
User entered '24 Feb 2021'	(b) (4) Cassie Uminski (b) (4) (b) (4)	10 Mar 2021 16:52:16

US3182065

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:38:18

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:38:00
DataPoint Verified.		01 Apr 2021 13:53:23
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:44:32
User entered '15:55'	(b) (4) Cassie Uminski (b) (4) (b) (4)	10 Mar 2021 16:52:16

US3182065

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:38:18

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:38:00
User entered '24 Feb 2021 15:55'	System	10 Mar 2021 16:52:16

US3182065

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:38:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:38:00
DataPoint Verified.		01 Apr 2021 13:53:28
User signature succeeded.	Mary Beth Manning	10 Mar 2021 21:44:32
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	10 Mar 2021 16:52:23

US3182065

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:38:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:38:00
User entered 'I'	System	10 Mar 2021 16:52:23

US3182065

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:39:28
DataPoint Verified.		08 Apr 2021 12:26:54
User signature succeeded.	Mary Beth Manning	30 Mar 2021 18:05:20
User entered 'Yes (Y)'	(b) (4) Brooke Glivar (b) (4) (b) (4)	30 Mar 2021 16:19:45

US3182065

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:18

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:39:28
DataPoint Verified.		08 Apr 2021 12:26:54
User signature succeeded.	Mary Beth Manning	30 Mar 2021 18:05:20
User entered '29 Mar 2021'	(b) (4) Brooke Glivar (b) (4) (b) (4)	30 Mar 2021 16:19:45

US3182065

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:39:28
DataPoint Verified.		08 Apr 2021 12:26:54
User signature succeeded.	Mary Beth Manning	30 Mar 2021 18:05:20
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Brooke Glivar (b) (4)	30 Mar 2021 16:19:45
	(b) (4)	

US3182065

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:39:28
DataPoint Verified.		08 Apr 2021 12:26:54
User signature succeeded.	Mary Beth Manning	30 Mar 2021 18:05:20
User entered empty.	(b) (4) Brooke Glivar (b) (4) (b) (4)	30 Mar 2021 16:19:45

US3182065

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:38:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:39:28
DataPoint Verified.		05 Apr 2021 21:24:11
User signature succeeded.	Mary Beth Manning	30 Mar 2021 18:05:20
User entered 'Yes (Y)'	(b) (4) Brooke Glivar (b) (4) (b) (4)	30 Mar 2021 16:19:48

US3182065

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:38:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 03:39:28
User entered 'I'	System	30 Mar 2021 16:19:48

US3182065

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:38:18

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:23:52
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	08 Feb 2021 19:27:51

US3182065

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:38:18

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:23:52
User entered '14 Jan 2021'	Cassie Uminski (b) (4) (b) (4)	08 Feb 2021 19:27:51

US3182065

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:38:18

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:23:52
User entered 'Clinic (Clinic)'	Cassie Uminski (b) (4) (b) (4)	08 Feb 2021 19:27:51

US3182065

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:38:18

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User entered 'UNBLND_DECIDE'	System	08 Feb 2021 19:27:51

US3182065

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:38:18

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:24:01
User entered '14 Jan 2021'	Cassie Uminski (b) (4) (b) (4)	08 Feb 2021 19:28:24

US3182065

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:38:18

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:11:20

US3182065

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:38:18

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:24:01
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	08 Feb 2021 19:28:24

US3182065

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:38:18

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:11:20

US3182065

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:38:18

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:24:01
User entered '14 Jan 2021'	Cassie Uminski (b) (4) (b) (4)	08 Feb 2021 19:28:24

US3182065

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:38:18

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:24:01
User entered 'Placebo (Placebo)'	Cassie Uminski (b) (4) (b) (4)	08 Feb 2021 19:28:24

US3182065

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:38:18

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:24:01
User entered 'Placebo (Placebo)'	Cassie Uminski (b) (4) (b) (4)	08 Feb 2021 19:28:24

US3182065

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:38:18

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:24:01
User entered 'Placebo (Placebo)'	Cassie Uminski (b) (4) (b) (4)	08 Feb 2021 19:28:24

US3182065

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:38:18

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:24:01
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	08 Feb 2021 19:28:24

US3182065

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:38:18

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User entered '1'	System	08 Feb 2021 19:28:24

US3182065

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:38:18

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User entered 'I'	System	08 Feb 2021 19:28:24

US3182065

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:38:18

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:25:22
User entered '166.0' cm	Cassie Uminski (b) (4) (b) (4)	08 Feb 2021 19:33:41

US3182065

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:38:18

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:25:22
User entered '66.2' kg	Cassie Uminski (b) (4) (b) (4)	08 Feb 2021 19:33:41

US3182065

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:38:18

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User entered '24.02381'	System	08 Feb 2021 19:33:41
DataPoint set to visible.	System	08 Feb 2021 19:28:24

US3182065

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:38:18

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:25:22
User entered '166.0' cm	Cassie Uminski (b) (4) (b) (4)	08 Feb 2021 19:33:41

US3182065

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:38:18

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:25:22
User entered '66.2' kg	Cassie Uminski (b) (4) (b) (4)	08 Feb 2021 19:33:41

US3182065

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:38:18

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User entered '24.02381'	System	08 Feb 2021 19:33:41
DataPoint set to visible.	System	08 Feb 2021 19:28:24

US3182065

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:18

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User accepted default value 'Pre-Dose (PREDOSE)'	Cassie Uminski (b) (4) (b) (4)	08 Feb 2021 19:33:41

US3182065

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:25:22
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	08 Feb 2021 19:33:41

US3182065

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:25:22
User entered '14 Jan 2021'	Cassie Uminski (b) (4) (b) (4)	08 Feb 2021 19:33:41

US3182065

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:18

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:25:22
User entered '14:00' reason for change: Data Entry Error	Cassie Uminski (b) (4)	10 Feb 2021 19:27:58
User entered '15:00'	(b) (4) Cassie Uminski (b) (4) (b) (4)	08 Feb 2021 19:33:41

US3182065

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:18

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User entered '14 Jan 2021 14:00'	System	10 Feb 2021 19:27:58
User entered '14 Jan 2021 15:00'	System	08 Feb 2021 19:33:41

US3182065

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:25:22
User entered '98.1' F	Cassie Uminski (b) (4) (b) (4)	08 Feb 2021 19:33:41

US3182065

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:25:22
User entered 'Oral (Oral)'	Cassie Uminski (b) (4) (b) (4)	08 Feb 2021 19:33:41

US3182065

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:25:22
User entered empty.	Cassie Uminski (b) (4) (b) (4)	08 Feb 2021 19:33:41

US3182065

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:25:22
User entered '77'	Cassie Uminski (b) (4) (b) (4)	08 Feb 2021 19:33:41

US3182065

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User entered 'bpm'	System	08 Feb 2021 19:33:41

US3182065

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:18

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:25:22
User entered '16'	Cassie Uminski (b) (4) (b) (4)	08 Feb 2021 19:33:41

US3182065

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User entered 'breaths/min'	System	08 Feb 2021 19:33:41

US3182065

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:18

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:25:22
User entered '129'	Cassie Uminski (b) (4) (b) (4)	08 Feb 2021 19:33:41

US3182065

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User entered 'mmHg'	System	08 Feb 2021 19:33:41

US3182065

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:18

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:25:22
User entered '81'	Cassie Uminski (b) (4) (b) (4)	08 Feb 2021 19:33:41

US3182065

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:18

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User entered 'mmHg'	System	08 Feb 2021 19:33:41

US3182065

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:38:18

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:25:22
User entered '166.0' cm	Cassie Uminski (b) (4) (b) (4)	08 Feb 2021 19:33:41

US3182065

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:38:18

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:25:22
User entered '66.2' kg	Cassie Uminski (b) (4) (b) (4)	08 Feb 2021 19:33:41

US3182065

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:38:18

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User entered '24.02381'	System	08 Feb 2021 19:33:41
DataPoint set to visible.	System	08 Feb 2021 19:28:24

US3182065

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:18

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User accepted default value 'Post-Dose (POSTDOSE)'	Cassie Uminski (b) (4) (b) (4)	08 Feb 2021 19:33:41

US3182065

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:25:22
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	08 Feb 2021 19:33:41

US3182065

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:25:22
User entered '14 Jan 2021'	Cassie Uminski (b) (4) (b) (4)	08 Feb 2021 19:33:41

US3182065

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:18

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:25:22
User entered '15:55'	Cassie Uminski (b) (4) (b) (4)	08 Feb 2021 19:33:41

US3182065

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:18

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User entered '14 Jan 2021 15:55'	System	08 Feb 2021 19:33:41

US3182065

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:25:22
User entered '98.3' F	Cassie Uminski (b) (4) (b) (4)	08 Feb 2021 19:33:41

US3182065

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:25:22
User entered 'Oral (Oral)'	Cassie Uminski (b) (4) (b) (4)	08 Feb 2021 19:33:41

US3182065

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:25:22
User entered empty.	Cassie Uminski (b) (4) (b) (4)	08 Feb 2021 19:33:41

US3182065

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:25:22
User entered '80'	Cassie Uminski (b) (4) (b) (4)	08 Feb 2021 19:33:41

US3182065

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User entered 'bpm'	System	08 Feb 2021 19:33:41

US3182065

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:18

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:25:22
User entered '16'	Cassie Uminski (b) (4) (b) (4)	08 Feb 2021 19:33:41

US3182065

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User entered 'breaths/min'	System	08 Feb 2021 19:33:41

US3182065

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:25:22
User entered '120'	Cassie Uminski (b) (4) (b) (4)	08 Feb 2021 19:33:41

US3182065

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User entered 'mmHg'	System	08 Feb 2021 19:33:41

US3182065

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:25:22
User entered '83'	Cassie Uminski (b) (4) (b) (4)	08 Feb 2021 19:33:41

US3182065

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:18

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User entered 'mmHg'	System	08 Feb 2021 19:33:41

US3182065

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:38:18

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:25:30
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	08 Feb 2021 19:34:11

US3182065

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:38:18

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:25:30
User entered '14 Jan 2021'	Cassie Uminski (b) (4) (b) (4)	08 Feb 2021 19:34:11

US3182065

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:38:18

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:25:39
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	08 Feb 2021 19:34:37

US3182065

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:38:18

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:25:39
User entered empty.	Cassie Uminski (b) (4) (b) (4)	08 Feb 2021 19:34:37

US3182065

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:38:18

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)	25 Apr 2021 08:58:35
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:25:39
User entered empty.	Cassie Uminski (b) (4) (b) (4)	08 Feb 2021 19:34:37

US3182065

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:38:18

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User entered 'mRNA-1273'	System	08 Feb 2021 19:34:37
DataPoint set to visible.	System	08 Feb 2021 19:28:24

US3182065

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:38:18

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:25:39
User entered '14 Jan 2021'	Cassie Uminski (b) (4) (b) (4)	08 Feb 2021 19:34:37

US3182065

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:38:18

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:25:39
User entered '15:24'	Cassie Uminski (b) (4) (b) (4)	08 Feb 2021 19:34:37

US3182065

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:38:18

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User entered '14 Jan 2021 15:24'	System	08 Feb 2021 19:34:37

US3182065

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:38:18

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:25:39
User entered 'Left Arm (LEFT ARM)'	Cassie Uminski (b) (4) (b) (4)	08 Feb 2021 19:34:37

US3182065

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:38:18

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
DataPoint Verified.		16 Feb 2021 14:25:39
User entered 'ONCE'	System	08 Feb 2021 19:34:37

US3182065

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:38:18

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User entered 'INTRAMUSCULAR'	System	08 Feb 2021 19:34:37

US3182065

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:38:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:23:43
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	08 Feb 2021 19:28:59

US3182065

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:38:18

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:23:43
User entered '14 Jan 2021'	Cassie Uminski (b) (4) (b) (4)	08 Feb 2021 19:28:59

US3182065

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:38:18

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:23:43
User entered '13:45'	Cassie Uminski (b) (4) (b) (4)	08 Feb 2021 19:28:59

US3182065

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:38:18

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User entered '14 Jan 2021 13:45'	System	08 Feb 2021 19:28:59

US3182065

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:38:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:23:21
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	08 Feb 2021 19:28:02

US3182065

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:38:18

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:23:21
User entered '14 Jan 2021'	Cassie Uminski (b) (4) (b) (4)	08 Feb 2021 19:28:02

US3182065

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:38:18

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:23:21
User entered '14:50'	Cassie Uminski (b) (4) (b) (4)	08 Feb 2021 19:28:02

US3182065

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:38:18

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User entered '14 Jan 2021 14:50'	System	08 Feb 2021 19:28:02

US3182065

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:38:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:23:46
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	08 Feb 2021 19:29:04

US3182065

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:38:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User entered 'I'	System	08 Feb 2021 19:29:04

US3182065

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:26:13
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	08 Feb 2021 19:35:27

US3182065

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:18

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:26:13
User entered '21 Jan 2021'	Cassie Uminski (b) (4) (b) (4)	08 Feb 2021 19:35:27

US3182065

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:26:13
User entered 'Contact Made (CONTACT MADE)'	Cassie Uminski (b) (4) (b) (4)	08 Feb 2021 19:35:27

US3182065

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:26:13
User entered empty.	Cassie Uminski (b) (4) (b) (4)	08 Feb 2021 19:35:27

US3182065

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:38:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:26:18
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	08 Feb 2021 19:35:32

US3182065

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:38:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User entered 'I'	System	08 Feb 2021 19:35:32

US3182065

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:38:18

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User entered '1'	System	08 Feb 2021 19:35:32
DataPoint set to visible.	System	08 Feb 2021 19:35:32

US3182065

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:38:18

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
DataPoint Verified.		01 Apr 2021 13:54:24
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:06:44
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	03 Mar 2021 16:35:16

US3182065

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:38:18

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
DataPoint Verified.		01 Apr 2021 13:54:24
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:06:44
User entered '24 Feb 2021'	(b) (4) Cassie Uminski (b) (4) (b) (4)	03 Mar 2021 16:35:16

US3182065

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:38:18

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
DataPoint Verified.		01 Apr 2021 13:54:24
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:06:44
User entered 'Clinic (Clinic)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	03 Mar 2021 16:35:16

US3182065

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:38:18

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User entered 'OLD29'	System	03 Mar 2021 16:35:16

US3182065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:18

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User accepted default value 'Pre-Dose (PREDOSE)'	Cassie Uminski (b) (4) (b) (4)	03 Mar 2021 16:39:45

US3182065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
DataPoint Verified.		01 Apr 2021 13:55:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:06:44
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	03 Mar 2021 16:39:45

US3182065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
DataPoint Verified.		01 Apr 2021 13:55:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:06:44
User entered '24 Feb 2021'	(b) (4) Cassie Uminski (b) (4) (b) (4)	03 Mar 2021 16:39:45

US3182065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:18

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
DataPoint Verified.		01 Apr 2021 13:55:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:06:44
User entered '16:07'	(b) (4) Cassie Uminski (b) (4) (b) (4)	03 Mar 2021 16:39:45

US3182065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:18

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User entered '24 Feb 2021 16:07'	System	03 Mar 2021 16:39:45

US3182065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
DataPoint Verified.		01 Apr 2021 13:55:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:06:44
	(b) (4)	
User entered '98.1' F	Cassie Uminski (b) (4)	03 Mar 2021 16:39:45
	(b) (4)	

US3182065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
DataPoint Verified.		01 Apr 2021 13:55:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:06:44
User entered 'Oral (Oral)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	03 Mar 2021 16:39:45

US3182065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
DataPoint Verified.		01 Apr 2021 13:55:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:06:44
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	03 Mar 2021 16:39:45
	(b) (4)	

US3182065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
DataPoint Verified.		01 Apr 2021 13:55:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:06:44
User entered '94'	(b) (4) Cassie Uminski (b) (4) (b) (4)	03 Mar 2021 16:39:45

US3182065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User entered 'bpm'	System	03 Mar 2021 16:39:45

US3182065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:18

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
DataPoint Verified.		01 Apr 2021 13:55:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:06:44
User entered '16'	(b) (4) Cassie Uminski (b) (4) (b) (4)	03 Mar 2021 16:39:45

US3182065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User entered 'breaths/min'	System	03 Mar 2021 16:39:45

US3182065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
DataPoint Verified.		01 Apr 2021 13:55:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:06:44
User entered '124'	(b) (4) Cassie Uminski (b) (4) (b) (4)	03 Mar 2021 16:39:45

US3182065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User entered 'mmHg'	System	03 Mar 2021 16:39:45

US3182065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
DataPoint Verified.		01 Apr 2021 13:55:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:06:44
User entered '81'	(b) (4) Cassie Uminski (b) (4) (b) (4)	03 Mar 2021 16:39:45

US3182065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:38:18

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User entered 'mmHg'	System	03 Mar 2021 16:39:45

US3182065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:18

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User accepted default value 'Post-Dose (POSTDOSE)'	Cassie Uminski (b) (4) (b) (4)	03 Mar 2021 16:39:45

US3182065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
DataPoint Verified.		01 Apr 2021 13:55:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:06:44
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	03 Mar 2021 16:39:45

US3182065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
DataPoint Verified.		01 Apr 2021 13:55:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:06:44
User entered '24 Feb 2021'	(b) (4) Cassie Uminski (b) (4) (b) (4)	03 Mar 2021 16:39:45

US3182065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:18

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
DataPoint Verified.		01 Apr 2021 13:55:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:06:44
User entered '16:45'	(b) (4) Cassie Uminski (b) (4) (b) (4)	03 Mar 2021 16:39:45

US3182065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:18

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User entered '24 Feb 2021 16:45'	System	03 Mar 2021 16:39:45

US3182065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
DataPoint Verified.		01 Apr 2021 13:55:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:06:44
	(b) (4)	
User entered '98.4' F	Cassie Uminski (b) (4)	03 Mar 2021 16:39:45
	(b) (4)	

US3182065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
DataPoint Verified.		01 Apr 2021 13:55:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:06:44
User entered 'Oral (Oral)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	03 Mar 2021 16:39:45

US3182065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
DataPoint Verified.		01 Apr 2021 13:55:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:06:44
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	03 Mar 2021 16:39:45
	(b) (4)	

US3182065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
DataPoint Verified.		01 Apr 2021 13:55:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:06:44
User entered '91'	(b) (4) Cassie Uminski (b) (4) (b) (4)	03 Mar 2021 16:39:45

US3182065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User entered 'bpm'	System	03 Mar 2021 16:39:45

US3182065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:18

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
DataPoint Verified.		01 Apr 2021 13:55:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:06:44
User entered '16'	(b) (4) Cassie Uminski (b) (4) (b) (4)	03 Mar 2021 16:39:45

US3182065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User entered 'breaths/min'	System	03 Mar 2021 16:39:45

US3182065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
DataPoint Verified.		01 Apr 2021 13:55:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:06:44
User entered '121'	(b) (4) Cassie Uminski (b) (4) (b) (4)	03 Mar 2021 16:39:45

US3182065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User entered 'mmHg'	System	03 Mar 2021 16:39:45

US3182065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
DataPoint Verified.		01 Apr 2021 13:55:32
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:06:44
User entered '78'	(b) (4) Cassie Uminski (b) (4) (b) (4)	03 Mar 2021 16:39:45

US3182065

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:38:18

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User entered 'mmHg'	System	03 Mar 2021 16:39:45

US3182065

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:38:18

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
DataPoint Verified.		01 Apr 2021 13:54:36
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:06:44
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	03 Mar 2021 16:40:09

US3182065

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:38:18

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
DataPoint Verified.		01 Apr 2021 13:54:36
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:06:44
User entered '24 Feb 2021'	(b) (4) Cassie Uminski (b) (4) (b) (4)	03 Mar 2021 16:40:09

US3182065

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:38:18

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
DataPoint Verified.		01 Apr 2021 13:54:43
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:06:44
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	03 Mar 2021 16:40:29

US3182065

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:38:18

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
DataPoint Verified.		01 Apr 2021 13:54:43
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:06:44
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	03 Mar 2021 16:40:29
	(b) (4)	

US3182065

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:38:18

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)	25 Apr 2021 08:58:35
DataPoint Verified.		01 Apr 2021 13:54:43
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:06:44
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	03 Mar 2021 16:40:29
	(b) (4)	

US3182065

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:38:18

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User entered 'mRNA-1273'	System	03 Mar 2021 16:40:29
DataPoint set to visible.	System	08 Feb 2021 19:35:32

US3182065

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:38:18

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
DataPoint Verified.		01 Apr 2021 13:54:43
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:06:44
User entered '24 Feb 2021'	(b) (4) Cassie Uminski (b) (4) (b) (4)	03 Mar 2021 16:40:29

US3182065

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:38:18

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
DataPoint Verified.		01 Apr 2021 13:54:43
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:06:44
	(b) (4)	
User entered '16:10'	Cassie Uminski (b) (4)	03 Mar 2021 16:40:29
	(b) (4)	

US3182065

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:38:18

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User entered '24 Feb 2021 16:10'	System	03 Mar 2021 16:40:29

US3182065

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:38:18

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
DataPoint Verified.		01 Apr 2021 13:54:43
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:06:44
	(b) (4)	
User entered 'Left Arm (LEFT ARM)'	Cassie Uminski (b) (4)	03 Mar 2021 16:40:29
	(b) (4)	

US3182065

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:38:18

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
DataPoint Verified.		01 Apr 2021 13:54:43
User entered 'ONCE'	System	03 Mar 2021 16:40:29

US3182065

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:38:18

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User entered 'INTRAMUSCULAR'	System	03 Mar 2021 16:40:29

US3182065

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:38:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
DataPoint Verified.		01 Apr 2021 13:54:48
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:06:44
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	03 Mar 2021 16:40:36

US3182065

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:38:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User entered 'I'	System	03 Mar 2021 16:40:36

US3182065

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:18

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
DataPoint Verified.		01 Apr 2021 13:55:50
User signature succeeded.	Mary Beth Manning	16 Mar 2021 17:00:00
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	15 Mar 2021 18:24:19

US3182065

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:18

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
DataPoint Verified.		01 Apr 2021 13:55:50
User signature succeeded.	Mary Beth Manning	16 Mar 2021 17:00:00
User entered '05 Mar 2021'	(b) (4) Cassie Uminski (b) (4) (b) (4)	15 Mar 2021 18:24:19

US3182065

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:18

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
DataPoint Verified.		01 Apr 2021 13:55:50
User signature succeeded.	Mary Beth Manning	16 Mar 2021 17:00:00
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Cassie Uminski (b) (4)	15 Mar 2021 18:24:19
	(b) (4)	

US3182065

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:38:18

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
DataPoint Verified.		01 Apr 2021 13:55:50
User signature succeeded.	Mary Beth Manning	16 Mar 2021 17:00:00
User entered empty.	(b) (4) Cassie Uminski (b) (4) (b) (4)	15 Mar 2021 18:24:19

US3182065

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:38:18

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
DataPoint Verified.		01 Apr 2021 13:55:55
User signature succeeded.	Mary Beth Manning	16 Mar 2021 17:00:00
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	15 Mar 2021 18:24:49

US3182065

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:38:18

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User entered 'I'	System	15 Mar 2021 18:24:49

US3182065

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:38:18

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
DataPoint Verified.		01 Apr 2021 13:56:04
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:34
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 17:52:45

US3182065

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:38:18

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
DataPoint Verified.		01 Apr 2021 13:56:04
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:34
User entered '24 Mar 2021'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 17:52:45

US3182065

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:38:18

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
DataPoint Verified.		01 Apr 2021 13:56:04
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:34
User entered 'Clinic (Clinic)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 17:52:45

US3182065

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:38:18

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User entered 'OLD57'	System	25 Mar 2021 17:52:45

US3182065

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:18

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
DataPoint Verified.		01 Apr 2021 13:56:23
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:34
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 17:53:37

US3182065

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:18

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
DataPoint Verified.		01 Apr 2021 13:56:23
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:34
User entered '24 Mar 2021'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 17:53:37

US3182065

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:18

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
DataPoint Verified.		01 Apr 2021 13:56:23
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:34
User entered '14:45'	(b) (4)	
	Cassie Uminski (b) (4)	25 Mar 2021 17:53:37
	(b) (4)	

US3182065

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:18

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User entered '24 Mar 2021 14:45'	System	25 Mar 2021 17:53:37

US3182065

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:18

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
DataPoint Verified.		01 Apr 2021 13:56:23
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:34
	(b) (4)	
User entered '98.2' F	Cassie Uminski (b) (4)	25 Mar 2021 17:53:37
	(b) (4)	

US3182065

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:18

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
DataPoint Verified.		01 Apr 2021 13:56:23
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:34
User entered 'Oral (Oral)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 17:53:37

US3182065

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:18

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
DataPoint Verified.		01 Apr 2021 13:56:23
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:34
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	25 Mar 2021 17:53:37
	(b) (4)	

US3182065

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:18

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
DataPoint Verified.		01 Apr 2021 13:56:23
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:34
User entered '108'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 17:53:37

US3182065

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:18

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User entered 'bpm'	System	25 Mar 2021 17:53:37

US3182065

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:18

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
DataPoint Verified.		01 Apr 2021 13:56:23
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:34
User entered '16'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 17:53:37

US3182065

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:18

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User entered 'breaths/min'	System	25 Mar 2021 17:53:37

US3182065

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:18

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
DataPoint Verified.		01 Apr 2021 13:56:23
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:34
User entered '113'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 17:53:37

US3182065

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:18

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User entered 'mmHg'	System	25 Mar 2021 17:53:37

US3182065

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:18

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
DataPoint Verified.		01 Apr 2021 13:56:23
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:34
User entered '76'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 17:53:37

US3182065

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:18

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User entered 'mmHg'	System	25 Mar 2021 17:53:37

US3182065

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:18

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35

US3182065

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:38:18

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35

US3182065

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:38:18

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
DataPoint Verified.		01 Apr 2021 13:56:34
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:34
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 17:54:16

US3182065

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:38:18

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
DataPoint Verified.		01 Apr 2021 13:56:34
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:34
User entered '24 Mar 2021'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 17:54:16

US3182065

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:38:18

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
DataPoint Verified.		01 Apr 2021 13:56:41
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:34
User entered 'Yes (Y)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 17:55:24

US3182065

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:38:18

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
DataPoint Verified.		01 Apr 2021 13:56:41
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:34
User entered '24 Mar 2021'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 17:55:24

US3182065

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:38:18

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
DataPoint Verified.		01 Apr 2021 13:56:41
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:34
User entered '15:00'	(b) (4)	
	Cassie Uminski (b) (4)	25 Mar 2021 17:55:24
	(b) (4)	

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:38:18

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 08:58:35
User entered '24 Mar 2021 15:00'	System	25 Mar 2021 17:55:24

US3182065

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:38:18

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:12:15
DataPoint Verified.		24 Mar 2021 12:24:12
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:06:44
DataPoint Un-verified.	(b) (4) Naqib Ahmad (b) (4)	16 Feb 2021 19:27:18
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Naqib Ahmad (b) (4)	16 Feb 2021 19:27:18
DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 14:26:26
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	04 Feb 2021 16:38:13

US3182065

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:38:18

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	14 Apr 2021 15:42:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:07:20
Reviewed for Safety.		26 Mar 2021 19:17:25
User entered 'USA-US075-2021-mRNA-1273-P301000006'	System	17 Feb 2021 15:44:16
User entered 'New'	(b) (4), (b) (6)	17 Feb 2021 15:44:16

US3182065

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:38:18

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Gastrointestinal neoplasms malignant and unspecified, HLT: Pancreatic neoplasms malignant (excl islet cell and carcinoid), PT: Pancreatic carcinoma stage IV, LLT: Pancreatic carcinoma stage IV - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Apr 2021 18:13:06
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Apr 2021 18:13:06
User signature succeeded.	Mary Beth Manning (b) (4)	14 Apr 2021 15:42:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:07:22
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Gastrointestinal neoplasms malignant and unspecified, HLT: Pancreatic neoplasms malignant (excl islet cell and carcinoid), PT: Pancreatic carcinoma, LLT: Pancreatic cancer - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	31 Mar 2021 12:01:24
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	31 Mar 2021 12:01:24
Data point term sent to Coder	System	25 Mar 2021 17:40:47
Coding entries removed.	Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 17:39:59
User entered 'Stage 4 PANCREATIC CANCER.' reason for change: Data Entry Error	Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 17:39:59
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Gastrointestinal neoplasms malignant and unspecified, HLT: Pancreatic neoplasms malignant (excl islet cell and carcinoid), PT: Pancreatic carcinoma, LLT: Pancreatic cancer - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Feb 2021 18:35:00
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Feb 2021 18:35:00
Data point term sent to Coder	System	16 Feb 2021 19:43:26
User entered 'Pancreatic Cancer.'	Naqib Ahmad (b) (4) (b) (4)	16 Feb 2021 19:42:47

US3182065

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:38:18

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	14 Apr 2021 15:42:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:07:24
User entered 'Yes (Y)'	Naqib Ahmad (b) (4) (b) (4)	16 Feb 2021 19:42:47

US3182065

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:38:18

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	14 Apr 2021 15:42:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:07:27
User entered 'No (N)'	Naqib Ahmad (b) (4) (b) (4)	16 Feb 2021 19:42:47

US3182065

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:38:18

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	14 Apr 2021 15:42:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:07:29
User entered 'No (N)'	Naqib Ahmad (b) (4) (b) (4)	16 Feb 2021 19:42:47

US3182065

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:38:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	14 Apr 2021 15:42:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:07:32
User entered '11 Feb 2021'	Naqib Ahmad (b) (4) (b) (4)	16 Feb 2021 19:42:47

US3182065

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:38:18

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	14 Apr 2021 15:42:23
DataPoint Verified.	(b) (4)	01 Apr 2021 13:07:35
	(b) (4), (b) (6)	
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	16 Feb 2021 19:43:20
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	16 Feb 2021 19:43:20
User entered empty; reason for change Data Entry Error	Naqib Ahmad (b) (4)	16 Feb 2021 19:43:20
	(b) (4)	
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	16 Feb 2021 19:42:47
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	16 Feb 2021 19:42:47
User entered 'uk:uk' (non-conformant).	Naqib Ahmad (b) (4)	16 Feb 2021 19:42:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:38:18

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Feb 2021 19:43:20
User entered '11 Feb 2021 UK:UK' (non-conformant).	System	16 Feb 2021 19:42:47

US3182065

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:38:18

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	14 Apr 2021 15:42:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:07:38
User entered 'Yes (Y)'	Naqib Ahmad (b) (4) (b) (4)	16 Feb 2021 19:42:47

US3182065

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:38:18

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the event end date, when available. Please note, if a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 14:25:05
Query 'PV Query: Please provide the event end date, when available. Please note, if a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' answered with 'Per PI, this is not a stable condition and is unlikely to stabilize. The information in EDC is correct as is' (Site from Safety).	Jennifer Gaston (b) (4)	22 Apr 2021 20:16:14
User opened query 'PV Query: Please provide the event end date, when available. Please note, if a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 14:46:04
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	14 Apr 2021 16:29:09
User signature succeeded.	Mary Beth Manning (b) (4)	14 Apr 2021 15:42:23
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please keep query open until resolution is achieved.' answered with 'Not recovered, still on-going - there is no end-date.' (Site from Safety).	Naqib Ahmad (b) (4)	13 Apr 2021 21:39:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:38:18

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:07:48
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please keep query open until resolution is achieved.' (Site from Safety).		11 Mar 2021 20:02:15
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).		11 Mar 2021 17:57:27
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'Correct as is, confirmed ongoing per source' (Site from Safety).	Cassie Uminski (b) (4) (b) (4)	10 Mar 2021 16:47:00
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 14:43:36
User entered empty.	Naqib Ahmad (b) (4) (b) (4)	16 Feb 2021 19:42:47

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:38:18

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	14 Apr 2021 15:42:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:07:52
User entered empty.	Naqib Ahmad (b) (4) (b) (4)	16 Feb 2021 19:42:47

US3182065

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:38:18

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Feb 2021 19:42:47

US3182065

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:38:18

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	14 Apr 2021 15:42:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:07:55
User entered 'Grade 3/Severe (Grade 3/Severe)'	Naqib Ahmad (b) (4) (b) (4)	16 Feb 2021 19:42:47

US3182065

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:38:18

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	14 Apr 2021 15:42:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:07:57
User entered 'Yes (Y)'	Naqib Ahmad (b) (4) (b) (4)	16 Feb 2021 19:42:47

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Folder: Adverse Events

Form: Adverse Events (1)

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[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	14 Apr 2021 15:42:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:08:12
User entered '0'	Naqib Ahmad (b) (4) (b) (4)	16 Feb 2021 19:42:47

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:38:18

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	14 Apr 2021 15:42:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:08:13
User entered '0'	Naqib Ahmad (b) (4) (b) (4)	16 Feb 2021 19:42:47

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Folder: Adverse Events

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	14 Apr 2021 15:42:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:08:15
User entered '0'	Naqib Ahmad (b) (4) (b) (4)	16 Feb 2021 19:42:47

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Folder: Adverse Events

Form: Adverse Events (1)

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	14 Apr 2021 15:42:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:08:17
User entered empty.	Naqib Ahmad (b) (4) (b) (4)	16 Feb 2021 19:42:47

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Folder: Adverse Events

Form: Adverse Events (1)

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	14 Apr 2021 15:42:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:08:19
User entered empty.	Naqib Ahmad (b) (4) (b) (4)	16 Feb 2021 19:42:47

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Folder: Adverse Events

Form: Adverse Events (1)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	14 Apr 2021 15:42:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:08:20
User entered empty.	Naqib Ahmad (b) (4) (b) (4)	16 Feb 2021 19:42:47

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	14 Apr 2021 15:42:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:08:22
User entered empty.	Naqib Ahmad (b) (4) (b) (4)	16 Feb 2021 19:42:47

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Folder: Adverse Events

Form: Adverse Events (1)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	14 Apr 2021 15:42:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:08:24
User entered '0'	Naqib Ahmad (b) (4) (b) (4)	16 Feb 2021 19:42:47

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:38:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	14 Apr 2021 15:42:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Apr 2021 13:08:25
User entered '0'	Naqib Ahmad (b) (4)	16 Feb 2021 19:42:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:38:18

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	14 Apr 2021 15:42:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:08:27
User entered 'I'	Naqib Ahmad (b) (4) (b) (4)	16 Feb 2021 19:42:47

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:38:18

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	14 Apr 2021 15:42:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:08:29
User entered 'Not Related (NOT RELATED)'	Naqib Ahmad (b) (4) (b) (4)	16 Feb 2021 19:42:47

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:38:18

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	14 Apr 2021 15:42:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:08:30
User entered 'Not Related (NOT RELATED)'	Naqib Ahmad (b) (4) (b) (4)	16 Feb 2021 19:42:47

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:38:18

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	14 Apr 2021 15:42:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Apr 2021 19:54:27
User closed query 'Should this be none as the second dose was given within window?' (Site from CRA).		11 Apr 2021 19:54:13
Query 'Should this be none as the second dose was given within window?' answered with 'Updated' (Site from CRA).	Cassie Uminski (b) (4) (b) (4)	09 Apr 2021 17:39:52
User entered 'None (NONE)' reason for change:	Cassie Uminski (b) (4)	09 Apr 2021 17:39:31
Data Entry Error	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	01 Apr 2021 13:11:45
User opened query 'Should this be none as the second dose was given within window?' (Site from CRA).		01 Apr 2021 13:11:43
DataPoint Verified.		01 Apr 2021 13:09:42
User entered 'Dose Delayed (DOSE DELAYED)'	Naqib Ahmad (b) (4) (b) (4)	16 Feb 2021 19:42:47

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:38:18

None

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	14 Apr 2021 15:42:23
User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #3 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Apr 2021 01:55:51
DataPoint Verified.	(b) (4), (b) (6)	11 Apr 2021 19:54:57
Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #3 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate. ' answered with 'Updated' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	09 Apr 2021 17:40:07
DataPoint Un-verified.	Cassie Uminski (b) (4) (b) (4)	09 Apr 2021 17:39:31
User entered '0' reason for change: Data Entry Error	Cassie Uminski (b) (4)	09 Apr 2021 17:39:31
User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #3 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Apr 2021 05:16:46
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:08:43
User entered '1'	Naqib Ahmad (b) (4) (b) (4)	16 Feb 2021 19:42:47

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:38:18

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	14 Apr 2021 15:42:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Apr 2021 19:54:39
DataPoint Un-verified.	Cassie Uminski (b) (4) (b) (4)	09 Apr 2021 17:39:31
User entered '1' reason for change: Data Entry Error	Cassie Uminski (b) (4)	09 Apr 2021 17:39:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:08:54
User entered '0'	Naqib Ahmad (b) (4) (b) (4)	16 Feb 2021 19:42:47

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:38:18

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 14:25:11
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'Records are pending at this time- will update upon receipt ' (Site from Safety).	Jennifer Gaston (b) (4)	22 Apr 2021 20:54:38
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)	19 Apr 2021 14:47:19
User signature succeeded.	Mary Beth Manning (b) (4)	14 Apr 2021 15:42:23
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:08:56
User entered '0'	Naqib Ahmad (b) (4)	16 Feb 2021 19:42:47

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:38:18

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	23 Apr 2021 15:17:48
User closed query 'PV Query: Please provide a response for the outcome in the eCRF. Please note, if the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 14:25:15
	(b) (4), (b) (6)	22 Apr 2021 21:04:51
User closed query 'You must have an answer here. It can be not resolved at this time but it must have an answer.' (Site from CRA).		22 Apr 2021 21:04:47
Query 'PV Query: Please provide a response for the outcome in the eCRF. Please note, if the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' answered with 'Per PI, not stabilized, and is unlikely to stablized.' (Site from Safety).	Jennifer Gaston (b) (4) (b) (4)	22 Apr 2021 20:54:09
Query 'You must have an answer here. It can be not resolved at this time but it must have an answer.' answered with 'updated' (Site from CRA).	Jennifer Gaston (b) (4) (b) (4)	22 Apr 2021 20:52:44
Signature has been broken.	Jennifer Gaston (b) (4) (b) (4)	22 Apr 2021 20:52:17
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Jennifer Gaston (b) (4) (b) (4)	22 Apr 2021 20:52:17
User opened query 'PV Query: Please provide a response for the outcome in the eCRF. Please note, if the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 14:46:33
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	19 Apr 2021 14:34:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:38:18

[Outcome](#)

Audit	User	Time (GMT)
User opened query 'You must have an answer here. It can be not resolved at this time but it must have an answer. ' (Site from CRA).	(b) (4), (b) (6)	18 Apr 2021 15:18:20
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).		14 Apr 2021 16:29:16
User signature succeeded.	Mary Beth Manning	14 Apr 2021 15:42:23
	(b) (4)	
Query 'Data is required. Please complete.' answered with 'On-going' (Site from System).	Naqib Ahmad (b) (4)	13 Apr 2021 21:39:29
	(b) (4)	
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'On-going' (Site from Safety).	Naqib Ahmad (b) (4)	13 Apr 2021 21:39:22
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Apr 2021 21:38:38
DataPoint Un-verified.	Naqib Ahmad (b) (4)	13 Apr 2021 21:38:38
	(b) (4)	
User entered empty; reason for change Data Entry Error	Naqib Ahmad (b) (4)	13 Apr 2021 21:38:38
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:08:57
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).		25 Feb 2021 14:42:42
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Naqib Ahmad (b) (4)	16 Feb 2021 19:42:47
	(b) (4)	

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	14 Apr 2021 15:42:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:09:09
User entered empty.	Naqib Ahmad (b) (4) (b) (4)	16 Feb 2021 19:42:47

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV query: Please provide description of initial symptoms leading to diagnosis of pancreatic cancer on 11 Feb 2021.' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 21:45:12
Query 'IQVIA Medical query: Please provide description of initial symptoms leading to diagnosis of pancreatic cancer on 11 Feb 2021. ' canceled (Site from Safety).		30 Apr 2021 21:44:14
User opened query 'PV query: Please provide medical records from Oncologist treating subject. Please leave query open until information is received.' (Site from Safety).		30 Apr 2021 21:40:18
User closed query 'IQVIA Medical query: Please provide medical records from Oncologist treating subject. ' (Site from Safety).		30 Apr 2021 14:06:28
Query 'IQVIA Medical query: Please provide medical records from Oncologist treating subject. ' answered with 'Medical records pending- records requested ' (Site from Safety).	Jennifer Gaston (b) (4) (b) (4)	29 Apr 2021 19:07:02
User opened query 'IQVIA Medical query: Please provide medical records from Oncologist treating subject. ' (Site from Safety).	(b) (4), (b) (6)	28 Apr 2021 16:59:26
User opened query 'IQVIA Medical query: Please provide description of initial symptoms leading to diagnosis of pancreatic cancer on 11 Feb 2021. ' (Site from Safety).		28 Apr 2021 16:59:18
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).		28 Apr 2021 16:59:08
User closed query 'IQVIA Medical query: Please provide description of initial symptoms leading to diagnosis of pancreatic cancer on 11 Feb 2021.' (Site from Safety).		23 Apr 2021 14:25:40
User closed query 'IQVIA Medical query: Please provide medical records from Oncologist treating subject.' (Site from Safety).		23 Apr 2021 14:25:29

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'IQVIA Medical query: Please provide medical records from Oncologist treating subject.' answered with 'Medical records are pending' (Site from Safety).	Jennifer Gaston (b) (4) (b) (4)	22 Apr 2021 20:53:31
Query 'IQVIA Medical query: Please provide description of initial symptoms leading to diagnosis of pancreatic cancer on 11 Feb 2021.' answered with 'unknown subject has not discussed w site ' (Site from Safety).	Jennifer Gaston (b) (4) (b) (4)	22 Apr 2021 20:53:08
User opened query 'IQVIA Medical query: Please provide medical records from Oncologist treating subject.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 14:45:23
User opened query 'IQVIA Medical query: Please provide description of initial symptoms leading to diagnosis of pancreatic cancer on 11 Feb 2021.' (Site from Safety).		19 Apr 2021 14:45:01
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' (Site from Safety).		14 Apr 2021 16:29:21
User signature succeeded.	Mary Beth Manning (b) (4)	14 Apr 2021 15:42:23
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' answered with 'Medical records to-be requested.' (Site from Safety).	Naqib Ahmad (b) (4) (b) (4)	13 Apr 2021 21:39:50
User closed query 'Per DM CLR: Narrative indicates that the subject had liver biopsy done. However, there is no corresponding Concomitant Procedure record that match the information. Please review and update to record the procedure as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6) (b) (4)	08 Apr 2021 10:24:17

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 13:10:35
	(b) (4), (b) (6)	01 Apr 2021 13:09:33
User closed 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).		26 Mar 2021 19:17:00
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	26 Mar 2021 19:16:57
Query 'Per DM CLR: Narrative indicates that the subject had liver biopsy done. However, there is no corresponding Concomitant Procedure record that match the information. Please review and update to record the procedure as appropriate. Otherwise, clarify.' answered with 'This will be updated once records are received' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 17:49:26
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.' answered with 'Updated' (Site from Safety).	Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 17:49:09

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT CALLED IN AND INFORMED US THAT SHE WAS JUST RECENTLY DIAGNOSED WITH PANCREATIC CANCER ON 11-FEB-2021. SHE WAS SCHEDULED TO PRESENT TO THIS SITE ON THAT SAME EXACT DAY (02/11/2021), HOWEVER, IT WAS CANCELLED BECAUSE SHE WAS HAVING A LIVER BIOPSY PERFORMED. SUBJECT HAS ENROLLED INTO OPEN LABEL PHASE, AND RECEIVED THE FIRST DOSE OF THE MRNA-1273 VACCINE/IP ON 14-JAN-2021 AT THIS SITE, AND IS NOW DUE FOR HER SECOND DOSE/DAY-28 VISIT. SUBJECT HAS Diagnosed with sage 4 pancreatic cancer and started chemotherapy on 3/17/2021. Medical records are pending.' reason for change: Data Entry Error	Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 17:48:56
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'Medical records are pending.' (Site from Safety).	Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 17:40:38
User opened query 'Per DM CLR: Narrative indicates that the subject had liver biopsy done. However, there is no corresponding Concomitant Procedure record that match the information. Please review and update to record the procedure as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	03 Mar 2021 02:22:49
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) (b) (4), (b) (6)	25 Feb 2021 14:43:59

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 14:42:22
User entered 'Subject called in and informed us that she was just recently diagnosed with pancreatic cancer on 11-FEB-2021. She was scheduled to present to this site on that same exact day (02/11/2021), however, it was cancelled because she was having a liver biopsy performed. Subject has enrolled into Open Label phase, and received the first dose of the mRNA-1273 vaccine/IP on 14-JAN-2021 at this site, and is now due for her second dose/Day-28 visit. Subject has not initiated any new medications or chemo-treatment as of right now and the staging of this new diagnosis is not yet known/confirmed.'	Naqib Ahmad (b) (4)	16 Feb 2021 19:42:47

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:38:18

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	16 Feb 2021 19:42:47

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Folder: Adverse Events

Form: Adverse Events (1)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Feb 2021 19:42:47

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:38:18

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:12:15
User closed query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' (Site from DM).		30 Mar 2021 07:20:35
Query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' answered with 'Updated' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 17:50:19
User opened query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 12:46:00
User signature succeeded.	Mary Beth Manning (b) (4)	09 Mar 2021 04:06:44
DataPoint Verified.	(b) (4), (b) (6)	18 Aug 2020 19:07:08
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:10:11

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:38:18

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:06:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 19:08:08
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Aug 2020 14:12:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Aug 2020 14:12:00
Data point term sent to Coder	System	04 Aug 2020 14:10:52
User entered 'Vitamin D'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:10:41

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:38:18

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:06:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 19:08:08
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:10:41

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:38:18

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:06:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 19:08:08
User entered 'Health Maintenance'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:10:41

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:38:18

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:06:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 19:08:08
User entered '1000'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:10:41

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:38:18

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:06:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 19:08:08
User entered 'IU (IU)'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:10:41

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:38:18

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:06:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 19:08:08
User entered empty.	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:10:41

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:38:18

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:06:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 19:08:08
User entered 'once daily (QD)'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:10:41

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:38:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:06:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 19:08:08
User entered empty.	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:10:41

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:38:18

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:06:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 19:08:08
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:10:41

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:38:18

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:06:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 19:08:08
User entered empty.	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:10:41

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:38:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:06:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 19:08:08
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).		12 Aug 2020 14:47:39
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	04 Aug 2020 14:10:41
User entered 'un Jan 2020'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:10:41

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:38:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:06:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 19:08:08
User entered '0'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:10:41

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:38:18

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:06:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 19:08:08
User entered 'Yes (Y)'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:10:41

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:38:18

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:06:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 19:08:08
User entered empty.	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:10:41

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:38:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:06:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Aug 2020 19:08:08
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	04 Aug 2020 14:10:41

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:38:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Aug 2020 14:10:41

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:38:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Aug 2020 14:10:41

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:38:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Aug 2020 14:10:41

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:38:18

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:47
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:06:44
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: MOTRIN [IBUPROFEN] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	10 Nov 2020 14:33:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 14:33:33
Data point term sent to Coder	System	10 Nov 2020 14:33:07
Coding entries removed.	Cassie Uminski (b) (4)	10 Nov 2020 14:32:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:29:46
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: MOTRIN [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 17:07:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 17:07:51
Data point term sent to Coder	System	25 Sep 2020 16:48:18
User entered 'Motrin'	Cassie Uminski (b) (4) (b) (4)	25 Sep 2020 16:48:12

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:38:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:47
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:06:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:29:46
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	25 Sep 2020 16:48:12

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:38:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:47
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:06:44
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Dec 2020 04:02:34
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria. ' answered with 'Does not meet AE reporting Criteria' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	16 Dec 2020 18:00:52

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:38:18

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 11:09:35
User closed query 'Per DM CLR: Please note that this condition is not recorded in the Adverse event ecrf or Diary. Please review Con Med use and add condition to AE ecrf as applicable. Else, provide clarification..' ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 11:43:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:18:20
Query 'Per DM CLR: Please note that this condition is not recorded in the Adverse event ecrf or Diary. Please review Con Med use and add condition to AE ecrf as applicable. Else, provide clarification..' ' answered with 'Updated' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	10 Nov 2020 14:32:11
DataPoint Un-verified.	Cassie Uminski (b) (4) (b) (4)	10 Nov 2020 14:32:06
User entered 'Headache' reason for change: Data Entry Error	Cassie Uminski (b) (4) (b) (4)	10 Nov 2020 14:32:06
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 16:29:46
User opened query 'Per DM CLR: Please note that this condition is not recorded in the Adverse event ecrf or Diary. Please review Con Med use and add condition to AE ecrf as applicable. Else, provide clarification..' ' (Site from DM).	(b) (4), (b) (6)	04 Oct 2020 06:19:01
User entered 'Injection site pain'	Cassie Uminski (b) (4) (b) (4)	25 Sep 2020 16:48:12

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:38:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:47
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:06:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:18:04
User closed query 'Please clarify as source for Day 36 safety call has 2 200 mg tablets. and only day 3 not 3 days. ' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 21:18:00
Query 'Please clarify as source for Day 36 safety call has 2 200 mg tablets. and only day 3 not 3 days. ' answered with 'Corrected.' (Site from CRA).	Amy Maroun (b) (4) (b) (4)	10 Nov 2020 20:29:25
DataPoint Un-verified.	Amy Maroun (b) (4) (b) (4)	10 Nov 2020 20:29:07
User entered '400' reason for change: Data Entry Error	Amy Maroun (b) (4) (b) (4)	10 Nov 2020 20:29:07
User opened query 'Please clarify as source for Day 36 safety call has 2 200 mg tablets. and only day 3 not 3 days. ' (Site from CRA).	(b) (4), (b) (6)	12 Oct 2020 16:32:09
DataPoint Verified.		12 Oct 2020 16:29:46
User entered '200'	Cassie Uminski (b) (4) (b) (4)	25 Sep 2020 16:48:12

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:38:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:47
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:06:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:29:46
User entered 'mg (mg)'	Cassie Uminski (b) (4) (b) (4)	25 Sep 2020 16:48:12

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:38:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:47
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:06:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:29:46
User entered empty.	Cassie Uminski (b) (4) (b) (4)	25 Sep 2020 16:48:12

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:38:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:47
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:06:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:29:46
User entered 'once daily (QD)'	Cassie Uminski (b) (4) (b) (4)	25 Sep 2020 16:48:12

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:38:18

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:47
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:06:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:29:46
User entered empty.	Cassie Uminski (b) (4) (b) (4)	25 Sep 2020 16:48:12

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:38:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:47
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:06:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:29:46
User entered 'Oral (ORAL)'	Cassie Uminski (b) (4) (b) (4)	25 Sep 2020 16:48:12

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:38:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:47
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:06:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:29:46
User entered empty.	Cassie Uminski (b) (4) (b) (4)	25 Sep 2020 16:48:12

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:38:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:47
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:06:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:12:54
DataPoint Un-verified.	Cassie Uminski (b) (4)	10 Nov 2020 14:31:40
User entered '30 Aug 2020' reason for change: Data Entry Error	(b) (4)	10 Nov 2020 14:31:40
DataPoint Verified.	(b) (4), (b) (6)	12 Oct 2020 16:29:46
User entered '29 Aug 2020'	Cassie Uminski (b) (4) (b) (4)	25 Sep 2020 16:48:12

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:38:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:47
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:06:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:29:46
User entered '0'	Cassie Uminski (b) (4) (b) (4)	25 Sep 2020 16:48:12

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:38:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:47
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:06:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:29:46
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	25 Sep 2020 16:48:12

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:38:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:47
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:06:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:29:46
User entered '30 Aug 2020'	Cassie Uminski (b) (4) (b) (4)	25 Sep 2020 16:48:12

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:38:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:47
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:06:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:18:13
User closed query 'Should this be yes since it is from the diary?' (Site from CRA).		10 Nov 2020 15:12:59
Query 'Should this be yes since it is from the diary?' answered with 'Updated' (Site from CRA).	Cassie Uminski (b) (4) (b) (4)	10 Nov 2020 14:29:50
User entered 'Yes (Y)' reason for change: Data Entry Error	Cassie Uminski (b) (4) (b) (4)	10 Nov 2020 14:27:39
DataPoint Un-verified.	(b) (4), (b) (6)	12 Oct 2020 16:29:51
DataPoint Verified.		12 Oct 2020 16:29:46
User opened query 'Should this be yes since it is from the diary?' (Site from CRA).		06 Oct 2020 17:19:51
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	25 Sep 2020 16:48:12

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:38:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:47
User entered '1'	System	25 Sep 2020 16:48:12

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:38:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:47
User entered '1'	System	25 Sep 2020 16:48:12

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:38:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:51:47
User entered '804 (804)'	System	25 Sep 2020 16:48:12

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:38:18

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: VARIOUS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, PRODUCT: ALL OTHER THERAPEUTIC PRODUCTS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 08:15:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 08:15:49
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:17:00
User signature succeeded.	Mary Beth Manning (b) (4)	26 Mar 2021 12:57:34
Data point term sent to Coder	System	25 Mar 2021 17:42:50
User entered 'Chemotherapy'	Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 17:42:40

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:38:18

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:17:00
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:34
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	25 Mar 2021 17:42:40
	(b) (4)	

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:38:18

Indication

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 01:56:06
Query 'Per DM CLR: Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification. ' answered with 'Updated' (Site from DM).	Cassie Uminski (b) (4) (b) (4)	09 Apr 2021 17:40:54
User opened query 'Per DM CLR: Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 05:20:38
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:17:00
User signature succeeded.	Mary Beth Manning (b) (4)	26 Mar 2021 12:57:34
User entered 'Pancreatic cancer'	Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 17:42:40

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:38:18

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:17:00
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:34
	(b) (4)	
User entered 'unknown'	Cassie Uminski (b) (4)	25 Mar 2021 17:42:40
	(b) (4)	

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:38:18

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:17:00
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:34
	(b) (4)	
User entered 'Other (OTHER)'	Cassie Uminski (b) (4)	25 Mar 2021 17:42:40
	(b) (4)	

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:38:18

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:17:00
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:34
	(b) (4)	
User entered 'Unknown'	Cassie Uminski (b) (4)	25 Mar 2021 17:42:40
	(b) (4)	

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:38:18

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:17:00
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:34
	(b) (4)	
User entered 'other (OTHER)'	Cassie Uminski (b) (4)	25 Mar 2021 17:42:40
	(b) (4)	

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:38:18

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:17:00
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:34
	(b) (4)	
User entered 'unknown'	Cassie Uminski (b) (4)	25 Mar 2021 17:42:40
	(b) (4)	

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:38:18

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:17:00
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:34
	(b) (4)	
User entered 'Other (OTHER)'	Cassie Uminski (b) (4)	25 Mar 2021 17:42:40
	(b) (4)	

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:38:18

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:17:00
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:34
	(b) (4)	
User entered 'Unknown'	Cassie Uminski (b) (4)	25 Mar 2021 17:42:40
	(b) (4)	

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:38:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:17:00
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:34
	(b) (4)	
User entered '17 Mar 2021'	Cassie Uminski (b) (4)	25 Mar 2021 17:42:40
	(b) (4)	

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:38:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:17:00
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:34
	(b) (4)	
User entered '0'	Cassie Uminski (b) (4)	25 Mar 2021 17:42:40
	(b) (4)	

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:38:18

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:17:00
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:34
	(b) (4)	
User entered 'Yes (Y)'	Cassie Uminski (b) (4)	25 Mar 2021 17:42:40
	(b) (4)	

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:38:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:17:00
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:34
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	25 Mar 2021 17:42:40
	(b) (4)	

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:38:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:17:00
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:34
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	25 Mar 2021 17:42:40
	(b) (4)	

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:38:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 17:42:40

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:38:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 17:42:40

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:38:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 17:42:40

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:38:18

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:38:34
User signature succeeded.	Mary Beth Manning	14 Apr 2021 15:42:23
User coded data point as ATC: DERMATOLOGICALS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICALS, PRODUCT: DURAPATITE, PRODUCTSYNONYM: RADIESSE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	14 Apr 2021 09:12:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 09:12:51
Data point term sent to Coder	System	13 Apr 2021 19:50:53
Coding entries removed.	Jennifer Gaston (b) (4) (b) (4)	13 Apr 2021 19:50:19
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:14:26
User closed query 'Should this be Radiesse instead of Rodiesse?' (Site from CRA).		12 Apr 2021 22:02:44
User coded data point as ATC: DERMATOLOGICALS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICALS, PRODUCT: DURAPATITE, PRODUCTSYNONYM: RADIESSE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 08:04:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 08:04:54
Data point term sent to Coder	System	09 Apr 2021 17:41:57
Query 'Should this be Radiesse instead of Rodiesse?' answered with 'Updated' (Site from CRA).	Cassie Uminski (b) (4) (b) (4)	09 Apr 2021 17:41:20
Coding entries removed.	Cassie Uminski (b) (4) (b) (4)	09 Apr 2021 17:41:15
Signature has been broken.	Cassie Uminski (b) (4) (b) (4)	09 Apr 2021 17:41:15

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:38:18

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'RaDIESSE' reason for change: Data Entry Error	Cassie Uminski (b) (4)	09 Apr 2021 17:41:15
User opened query 'Should this be Radiesse instead of Rodiesse? ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	01 Apr 2021 13:19:15
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:34
User coded data point as ATC: DERMATOLOGICALS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICALS, PRODUCT: DURAPATITE, PRODUCTSYNONYM: RADIESSE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	26 Mar 2021 11:55:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Mar 2021 11:55:43
Data point term sent to Coder	System	25 Mar 2021 17:43:51
User entered 'Rodiesse'	Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 17:43:26

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:38:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:38:34
DataPoint Verified.		13 Apr 2021 17:14:32
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:34
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 17:43:26

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:38:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:38:34
DataPoint Verified.		13 Apr 2021 17:14:33
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:34
User entered 'Cosmetic Facial Filler'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 17:43:26

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:38:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:38:34
DataPoint Verified.		13 Apr 2021 17:14:42
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:34
User entered 'unknown'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 17:43:26

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:38:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:38:34
DataPoint Verified.		13 Apr 2021 17:14:46
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:34
User entered 'Other (OTHER)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 17:43:26

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:38:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:38:34
DataPoint Verified.		13 Apr 2021 17:14:48
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:34
User entered 'unknown'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 17:43:26

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:38:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:38:34
DataPoint Verified.		13 Apr 2021 17:14:49
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:34
User entered 'other (OTHER)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 17:43:26

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:38:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:38:34
DataPoint Verified.		13 Apr 2021 17:14:52
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:34
User entered 'Every 12-14 months'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 17:43:26

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:38:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:38:34
User signature succeeded.	Mary Beth Manning	14 Apr 2021 15:42:23
User closed query 'Should this be percutaneous instead of subcutaneous per manufacturers website? ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	14 Apr 2021 12:21:29
DataPoint Verified.		14 Apr 2021 12:21:05
Query 'Should this be percutaneous instead of subcutaneous per manufacturers website? ' answered with 'confirmed, updated' (Site from CRA).	Jennifer Gaston (b) (4) (b) (4)	13 Apr 2021 19:50:40
Signature has been broken.	Jennifer Gaston (b) (4) (b) (4)	13 Apr 2021 19:50:19
User entered 'Other (OTHER)' reason for change: Data Entry Error	Jennifer Gaston (b) (4) (b) (4)	13 Apr 2021 19:50:19
User opened query 'Should this be percutaneous instead of subcutaneous per manufacturers website? ' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 17:15:33
User signature succeeded.	Mary Beth Manning (b) (4)	26 Mar 2021 12:57:34
User entered 'Subcutaneous (SUBCUTANEOUS)'	Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 17:43:26

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:38:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:38:34
User signature succeeded.	Mary Beth Manning	14 Apr 2021 15:42:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 12:21:17
DataPoint Un-verified.	Jennifer Gaston (b) (4)	13 Apr 2021 19:50:19
Signature has been broken.	(b) (4) Jennifer Gaston (b) (4)	13 Apr 2021 19:50:19
User entered 'Percutaneous' reason for change: Data Entry Error	(b) (4) Jennifer Gaston (b) (4)	13 Apr 2021 19:50:19
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:15:38
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:34
User entered empty.	(b) (4) Cassie Uminski (b) (4)	25 Mar 2021 17:43:26

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:38:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:38:34
DataPoint Verified.		13 Apr 2021 17:15:46
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:34
User entered 'un UNK 2015'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 17:43:26

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:38:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:38:34
DataPoint Verified.		13 Apr 2021 17:15:48
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:34
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 17:43:26

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:38:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:38:34
DataPoint Verified.		13 Apr 2021 17:15:51
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:34
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	25 Mar 2021 17:43:26
	(b) (4)	

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:38:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:38:34
DataPoint Verified.		13 Apr 2021 17:15:53
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:34
User entered 'un Jun 2020'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 17:43:26

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:38:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:38:34
DataPoint Verified.		13 Apr 2021 17:15:57
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:34
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	25 Mar 2021 17:43:26
	(b) (4)	

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:38:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:38:34
User entered empty.	System	25 Mar 2021 17:43:26

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:38:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:38:34
User entered empty.	System	25 Mar 2021 17:43:26

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:38:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:38:34
User entered empty.	System	25 Mar 2021 17:43:26

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:38:18

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:38:39
DataPoint Verified.		06 Apr 2021 15:24:02
User coded data point as ATC: DERMATOLOGICALS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICALS, PRODUCT: HYALURONIC ACID, PRODUCTS JUVEDERM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Mar 2021 14:29:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Mar 2021 14:29:13
User signature succeeded.	Mary Beth Manning (b) (4)	26 Mar 2021 12:57:34
Data point term sent to Coder	System	25 Mar 2021 17:44:51
User entered 'Juvederm'	Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 17:44:27

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:38:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:38:39
DataPoint Verified.		06 Apr 2021 15:24:02
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:34
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	25 Mar 2021 17:44:27
	(b) (4)	

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:38:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:38:39
DataPoint Verified.		06 Apr 2021 15:24:02
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:34
	(b) (4)	
User entered 'Cosmetic Facial Filler'	Cassie Uminski (b) (4)	25 Mar 2021 17:44:27
	(b) (4)	

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:38:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:38:39
DataPoint Verified.		06 Apr 2021 15:24:02
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:34
User entered 'unknown'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 17:44:27

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:38:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:38:39
DataPoint Verified.		06 Apr 2021 15:24:02
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:34
	(b) (4)	
User entered 'Other (OTHER)'	Cassie Uminski (b) (4)	25 Mar 2021 17:44:27
	(b) (4)	

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:38:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:38:39
DataPoint Verified.		06 Apr 2021 15:24:02
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:34
	(b) (4)	
User entered 'Unknown'	Cassie Uminski (b) (4)	25 Mar 2021 17:44:27
	(b) (4)	

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:38:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:38:39
DataPoint Verified.		06 Apr 2021 15:24:02
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:34
	(b) (4)	
User entered 'other (OTHER)'	Cassie Uminski (b) (4)	25 Mar 2021 17:44:27
	(b) (4)	

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:38:18

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:38:39
DataPoint Verified.		06 Apr 2021 15:24:02
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:34
User entered 'Every 12-14 months'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 17:44:27

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:38:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:38:39
DataPoint Verified.		06 Apr 2021 15:24:02
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:34
	(b) (4)	
User entered 'Subcutaneous (SUBCUTANEOUS)'	Cassie Uminski (b) (4)	25 Mar 2021 17:44:27
	(b) (4)	

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:38:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:38:39
DataPoint Verified.		06 Apr 2021 15:24:02
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:34
	(b) (4)	
User entered empty.	Cassie Uminski (b) (4)	25 Mar 2021 17:44:27
	(b) (4)	

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:38:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:38:39
DataPoint Verified.		06 Apr 2021 15:24:02
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:34
User entered 'un UNK 2015'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 17:44:27

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:38:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:38:39
DataPoint Verified.		06 Apr 2021 15:24:02
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:34
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 17:44:27

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:38:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:38:39
DataPoint Verified.		06 Apr 2021 15:24:02
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:34
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	25 Mar 2021 17:44:27
	(b) (4)	

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:38:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:38:39
DataPoint Verified.		06 Apr 2021 15:24:02
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:34
	(b) (4)	
User entered 'un Jun 2020'	Cassie Uminski (b) (4)	25 Mar 2021 17:44:27
	(b) (4)	

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:38:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:38:39
DataPoint Verified.		06 Apr 2021 15:24:02
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:34
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 17:44:27

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:38:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:38:39
User entered empty.	System	25 Mar 2021 17:44:27

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:38:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:38:39
User entered empty.	System	25 Mar 2021 17:44:27

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:38:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:38:39
User entered empty.	System	25 Mar 2021 17:44:27

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:38:18

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:38:43
User coded data point as ATC: DERMATOLOGICALS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICALS, PRODUCT: BOTULINUM TOXIN TYPE A, PRODUCTSYNONYM: BOTOX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 01:36:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 01:36:44
Data point term sent to Coder	System	19 Apr 2021 19:08:20
Coding entries removed.	Cassie Uminski (b) (4) (b) (4)	19 Apr 2021 19:08:04
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:16:08
User coded data point as ATC: DERMATOLOGICALS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICALS, PRODUCT: BOTULINUM TOXIN TYPE A, PRODUCTSYNONYM: BOTOX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Mar 2021 13:16:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Mar 2021 13:16:56
User signature succeeded.	Mary Beth Manning (b) (4)	26 Mar 2021 12:57:34
Data point term sent to Coder	System	25 Mar 2021 17:46:53
User entered 'Botox'	Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 17:46:21

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:38:18

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:38:43
DataPoint Verified.		13 Apr 2021 17:16:11
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:34
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	25 Mar 2021 17:46:21
	(b) (4)	

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:38:18

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:38:43
DataPoint Verified.		13 Apr 2021 17:16:12
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:34
User entered 'Cosmetic Facial Filler'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 17:46:21

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:38:18

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:38:43
DataPoint Verified.		13 Apr 2021 17:16:15
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:34
	(b) (4)	
User entered 'unknown'	Cassie Uminski (b) (4)	25 Mar 2021 17:46:21
	(b) (4)	

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:38:18

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:38:43
DataPoint Verified.		13 Apr 2021 17:16:17
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:34
	(b) (4)	
User entered 'Other (OTHER)'	Cassie Uminski (b) (4)	25 Mar 2021 17:46:21
	(b) (4)	

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:38:18

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:38:43
DataPoint Verified.		13 Apr 2021 17:16:19
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:34
User entered 'Unknown'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 17:46:21

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:38:18

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:38:43
DataPoint Verified.		13 Apr 2021 17:16:20
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:34
	(b) (4)	
User entered 'other (OTHER)'	Cassie Uminski (b) (4)	25 Mar 2021 17:46:21
	(b) (4)	

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:38:18

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:38:43
DataPoint Verified.		13 Apr 2021 17:16:22
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:34
	(b) (4)	
User entered 'Every 12-14 months'	Cassie Uminski (b) (4)	25 Mar 2021 17:46:21
	(b) (4)	

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:38:18

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:38:43
User signature succeeded.	Toby Briskin (b) (4)	20 Apr 2021 13:55:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 19:37:23
User closed query 'Please clarify as manufacturer's website says it is used IM, not SQ. ' (Site from CRA).		19 Apr 2021 19:37:21
Signature has been broken.	Cassie Uminski (b) (4)	19 Apr 2021 19:08:04
User entered 'Intramuscular (INTRAMUSCULAR)' reason for change: Data Entry Error	(b) (4) Cassie Uminski (b) (4)	19 Apr 2021 19:08:04
Query 'Please clarify as manufacturer's website says it is used IM, not SQ. ' answered with 'per indication confirmed correct as is' (Site from CRA).	(b) (4) Jennifer Gaston (b) (4)	13 Apr 2021 19:52:04
User opened query 'Please clarify as manufacturer's website says it is used IM, not SQ. ' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 17:17:08
User closed query 'Please clarify if this should be IM' (Site from CRA).		13 Apr 2021 17:17:08
Query 'Please clarify if this should be IM' answered with 'Correct as is' (Site from CRA).	Cassie Uminski (b) (4)	09 Apr 2021 17:42:38
User opened query 'Please clarify if this should be IM' (Site from CRA).	(b) (4) (b) (4), (b) (6)	02 Apr 2021 18:21:47
User signature succeeded.	Mary Beth Manning (b) (4)	26 Mar 2021 12:57:34
User entered 'Subcutaneous (SUBCUTANEOUS)'	Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 17:46:21

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:38:18

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:38:43
DataPoint Verified.		13 Apr 2021 17:16:25
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:34
User entered empty.	(b) (4)	
	Cassie Uminski (b) (4)	25 Mar 2021 17:46:21
	(b) (4)	

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:38:18

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:38:43
DataPoint Verified.		13 Apr 2021 17:16:27
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:34
User entered 'un UNK 2015'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 17:46:21

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:38:18

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:38:43
DataPoint Verified.		13 Apr 2021 17:16:28
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:34
User entered '0'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 17:46:21

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:38:18

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:38:43
DataPoint Verified.		13 Apr 2021 17:16:30
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:34
	(b) (4)	
User entered 'No (N)'	Cassie Uminski (b) (4)	25 Mar 2021 17:46:21
	(b) (4)	

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:38:18

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:38:43
DataPoint Verified.		13 Apr 2021 17:16:32
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:34
User entered 'un Jun 2020'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 17:46:21

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:38:18

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:38:43
DataPoint Verified.		13 Apr 2021 17:16:35
User signature succeeded.	Mary Beth Manning	26 Mar 2021 12:57:34
User entered 'No (N)'	(b) (4) Cassie Uminski (b) (4) (b) (4)	25 Mar 2021 17:46:21

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:38:18

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:38:43
User entered empty.	System	25 Mar 2021 17:46:21

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:38:18

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:38:43
User entered empty.	System	25 Mar 2021 17:46:21

US3182065

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:38:18

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:38:43
User entered empty.	System	25 Mar 2021 17:46:21

US3182065

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:38:18

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:06:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 14:26:36
User entered 'No (N)'	Cassie Uminski (b) (4) (b) (4)	04 Feb 2021 16:38:18

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:57:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:44:31
User entered	System	17 Feb 2021 15:44:16
'USA-US075-2021-MRNA-1273-P301000006'		

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:57:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:44:31
User entered 'Yes (Y)'	System	17 Feb 2021 15:44:16

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:57:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:44:31
User entered 'No (N)'	System	17 Feb 2021 15:44:16

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:57:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:44:31
User entered 'No (N)'	System	17 Feb 2021 15:44:16

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:57:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:44:31
User entered 'No (N)'	System	17 Feb 2021 15:44:16

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:57:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:44:31
User entered 'No (N)'	System	17 Feb 2021 15:44:16

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:57:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:44:31
User entered 'No (N)'	System	17 Feb 2021 15:44:16

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:57:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:44:31
User entered 'Yes (Y)'	System	17 Feb 2021 15:44:16

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 16:28:09
DataPoint Verified.		13 Apr 2021 17:13:14
User signature succeeded.	Toby Briskin (b) (4)	12 Apr 2021 20:01:06
Un-reviewed for Safety.	(b) (4)	
System		12 Apr 2021 15:21:09
Signature has been broken.	System	12 Apr 2021 15:21:09
User entered 'Toby'	System	12 Apr 2021 15:21:09
DataPoint Un-verified.	(b) (4), (b) (6)	01 Apr 2021 13:57:43
DataPoint Verified.		01 Apr 2021 13:57:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	17 Feb 2021 15:44:31
User entered 'Jennifer'	System	17 Feb 2021 15:44:16

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 16:28:09
DataPoint Verified.		13 Apr 2021 17:13:14
User signature succeeded.	Toby Briskin (b) (4)	12 Apr 2021 20:01:06
Un-reviewed for Safety.	(b) (4)	
System		12 Apr 2021 15:21:09
Signature has been broken.	System	12 Apr 2021 15:21:09
User entered 'Briskin'	System	12 Apr 2021 15:21:09
DataPoint Un-verified.	(b) (4), (b) (6)	01 Apr 2021 13:57:45
DataPoint Verified.		01 Apr 2021 13:57:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	17 Feb 2021 15:44:31
User entered 'Gaston'	System	17 Feb 2021 15:44:16

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

Site Address: [Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 16:28:09
DataPoint Verified.		13 Apr 2021 17:13:14
User signature succeeded.	Toby Briskin (b) (4)	12 Apr 2021 20:01:06
User entered '3619 Park East Drive, Suite 300'	(b) (4) System	12 Apr 2021 15:21:09

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

Site Address: [City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 16:28:09
DataPoint Verified.		13 Apr 2021 17:13:14
User signature succeeded.	Toby Briskin (b) (4)	12 Apr 2021 20:01:06
User entered 'Beachwood'	(b) (4) System	12 Apr 2021 15:21:09

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:57:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:44:31
User entered 'OH'	System	17 Feb 2021 15:44:16

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 16:28:09
DataPoint Verified.		13 Apr 2021 17:13:14
User signature succeeded.	Toby Briskin (b) (4)	12 Apr 2021 20:01:06
User entered '44122'	(b) (4) System	12 Apr 2021 15:21:09

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:57:41
Reviewed for Safety.		26 Mar 2021 19:18:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
User entered 'US'	(b) (4) System	17 Feb 2021 15:44:56

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	23 Apr 2021 14:26:39
User entered '4'	System	14 Apr 2021 16:27:32
User entered '3'	System	12 Apr 2021 15:21:09
User entered '2'	System	26 Mar 2021 19:19:04
User entered '1'	System	17 Feb 2021 15:44:56

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:57:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:44:31
User entered	System	17 Feb 2021 15:44:16
'USA-US075-2021-MRNA-1273-P301000006'		

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:57:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:44:31
User entered 'Yes (Y)'	System	17 Feb 2021 15:44:16

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:57:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:44:31
User entered 'No (N)'	System	17 Feb 2021 15:44:16

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:57:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:44:31
User entered 'No (N)'	System	17 Feb 2021 15:44:16

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:57:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:44:31
User entered 'No (N)'	System	17 Feb 2021 15:44:16

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:57:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:44:31
User entered 'No (N)'	System	17 Feb 2021 15:44:16

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:57:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:44:31
User entered 'No (N)'	System	17 Feb 2021 15:44:16

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:57:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:44:31
User entered 'Yes (Y)'	System	17 Feb 2021 15:44:16

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 16:28:09
DataPoint Verified.		13 Apr 2021 17:13:14
User signature succeeded.	Toby Briskin (b) (4)	12 Apr 2021 20:01:06
Un-reviewed for Safety.	(b) (4)	
System		12 Apr 2021 15:21:09
Signature has been broken.	System	12 Apr 2021 15:21:09
User entered 'Toby'	System	12 Apr 2021 15:21:09
DataPoint Un-verified.	(b) (4), (b) (6)	01 Apr 2021 13:57:43
DataPoint Verified.		01 Apr 2021 13:57:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	17 Feb 2021 15:44:31
User entered 'Jennifer'	System	17 Feb 2021 15:44:16

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 16:28:09
DataPoint Verified.		13 Apr 2021 17:13:14
User signature succeeded.	Toby Briskin (b) (4)	12 Apr 2021 20:01:06
Un-reviewed for Safety.	(b) (4)	
System		12 Apr 2021 15:21:09
Signature has been broken.	System	12 Apr 2021 15:21:09
User entered 'Briskin'	System	12 Apr 2021 15:21:09
DataPoint Un-verified.	(b) (4), (b) (6)	01 Apr 2021 13:57:45
DataPoint Verified.		01 Apr 2021 13:57:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	17 Feb 2021 15:44:31
User entered 'Gaston'	System	17 Feb 2021 15:44:16

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

Site Address: [Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 16:28:09
DataPoint Verified.		13 Apr 2021 17:13:14
User signature succeeded.	Toby Briskin (b) (4)	12 Apr 2021 20:01:06
User entered '3619 Park East Drive, Suite 300'	(b) (4) System	12 Apr 2021 15:21:09

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

Site Address: [City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 16:28:09
DataPoint Verified.		13 Apr 2021 17:13:14
User signature succeeded.	Toby Briskin (b) (4)	12 Apr 2021 20:01:06
User entered 'Beachwood'	(b) (4) System	12 Apr 2021 15:21:09

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:57:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:44:31
User entered 'OH'	System	17 Feb 2021 15:44:16

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 16:28:09
DataPoint Verified.		13 Apr 2021 17:13:14
User signature succeeded.	Toby Briskin (b) (4)	12 Apr 2021 20:01:06
User entered '44122'	(b) (4) System	12 Apr 2021 15:21:09

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:57:41
Reviewed for Safety.		26 Mar 2021 19:18:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
User entered 'US'	(b) (4) System	17 Feb 2021 15:44:56

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	23 Apr 2021 14:26:39
User entered '4'	System	14 Apr 2021 16:27:32
User entered '3'	System	12 Apr 2021 15:21:09
User entered '2'	System	26 Mar 2021 19:19:04
User entered '1'	System	17 Feb 2021 15:44:56

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:38:18

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:57:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
	(b) (4)	
User entered '17/Feb/2021 10:44'	System	17 Feb 2021 15:44:56

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:38:18

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)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:57:41
Reviewed for Safety.		26 Mar 2021 19:18:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
User entered 'I'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 15:44:56

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:57:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:44:31
User entered	System	17 Feb 2021 15:44:16
'USA-US075-2021-MRNA-1273-P301000006'		

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:57:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:44:31
User entered 'Yes (Y)'	System	17 Feb 2021 15:44:16

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:57:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:44:31
User entered 'No (N)'	System	17 Feb 2021 15:44:16

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:57:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:44:31
User entered 'No (N)'	System	17 Feb 2021 15:44:16

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:57:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:44:31
User entered 'No (N)'	System	17 Feb 2021 15:44:16

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:57:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:44:31
User entered 'No (N)'	System	17 Feb 2021 15:44:16

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:57:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:44:31
User entered 'No (N)'	System	17 Feb 2021 15:44:16

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:57:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:44:31
User entered 'Yes (Y)'	System	17 Feb 2021 15:44:16

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 16:28:09
DataPoint Verified.		13 Apr 2021 17:13:14
User signature succeeded.	Toby Briskin (b) (4)	12 Apr 2021 20:01:06
Un-reviewed for Safety.	(b) (4)	
System		12 Apr 2021 15:21:09
Signature has been broken.	System	12 Apr 2021 15:21:09
User entered 'Toby'	System	12 Apr 2021 15:21:09
DataPoint Un-verified.	(b) (4), (b) (6)	01 Apr 2021 13:57:43
DataPoint Verified.		01 Apr 2021 13:57:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	17 Feb 2021 15:44:31
User entered 'Jennifer'	System	17 Feb 2021 15:44:16

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 16:28:09
DataPoint Verified.		13 Apr 2021 17:13:14
User signature succeeded.	Toby Briskin (b) (4)	12 Apr 2021 20:01:06
Un-reviewed for Safety.	(b) (4)	
System		12 Apr 2021 15:21:09
Signature has been broken.	System	12 Apr 2021 15:21:09
User entered 'Briskin'	System	12 Apr 2021 15:21:09
DataPoint Un-verified.	(b) (4), (b) (6)	01 Apr 2021 13:57:45
DataPoint Verified.		01 Apr 2021 13:57:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	17 Feb 2021 15:44:31
User entered 'Gaston'	System	17 Feb 2021 15:44:16

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

Site Address: [Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 16:28:09
DataPoint Verified.		13 Apr 2021 17:13:14
User signature succeeded.	Toby Briskin (b) (4)	12 Apr 2021 20:01:06
User entered '3619 Park East Drive, Suite 300'	(b) (4) System	12 Apr 2021 15:21:09

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

Site Address: [City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 16:28:09
DataPoint Verified.		13 Apr 2021 17:13:14
User signature succeeded.	Toby Briskin (b) (4)	12 Apr 2021 20:01:06
User entered 'Beachwood'	(b) (4) System	12 Apr 2021 15:21:09

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:57:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:44:31
User entered 'OH'	System	17 Feb 2021 15:44:16

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 16:28:09
DataPoint Verified.		13 Apr 2021 17:13:14
User signature succeeded.	Toby Briskin (b) (4)	12 Apr 2021 20:01:06
User entered '44122'	(b) (4) System	12 Apr 2021 15:21:09

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:57:41
Reviewed for Safety.		26 Mar 2021 19:18:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
User entered 'US'	(b) (4) System	17 Feb 2021 15:44:56

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	23 Apr 2021 14:26:39
User entered '4'	System	14 Apr 2021 16:27:32
User entered '3'	System	12 Apr 2021 15:21:09
User entered '2'	System	26 Mar 2021 19:19:04
User entered '1'	System	17 Feb 2021 15:44:56

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:38:18

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:57:41
User signature succeeded.	Mary Beth Manning	27 Mar 2021 16:56:39
	(b) (4)	
User entered '26/Mar/2021 19:19'	System	26 Mar 2021 19:19:04

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:38:18

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 15:20:54
DataPoint Verified.		01 Apr 2021 13:57:41
User signature succeeded.	Mary Beth Manning	27 Mar 2021 16:56:39
User entered 'I'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 19:19:04

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:57:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:44:31
User entered	System	17 Feb 2021 15:44:16
'USA-US075-2021-MRNA-1273-P301000006'		

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:57:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:44:31
User entered 'Yes (Y)'	System	17 Feb 2021 15:44:16

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:57:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:44:31
User entered 'No (N)'	System	17 Feb 2021 15:44:16

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:57:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:44:31
User entered 'No (N)'	System	17 Feb 2021 15:44:16

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:57:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:44:31
User entered 'No (N)'	System	17 Feb 2021 15:44:16

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:57:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:44:31
User entered 'No (N)'	System	17 Feb 2021 15:44:16

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:57:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:44:31
User entered 'No (N)'	System	17 Feb 2021 15:44:16

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:57:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:44:31
User entered 'Yes (Y)'	System	17 Feb 2021 15:44:16

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 16:28:09
DataPoint Verified.		13 Apr 2021 17:13:14
User signature succeeded.	Toby Briskin (b) (4)	12 Apr 2021 20:01:06
Un-reviewed for Safety.	(b) (4)	
System		12 Apr 2021 15:21:09
Signature has been broken.	System	12 Apr 2021 15:21:09
User entered 'Toby'	System	12 Apr 2021 15:21:09
DataPoint Un-verified.	(b) (4), (b) (6)	01 Apr 2021 13:57:43
DataPoint Verified.		01 Apr 2021 13:57:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	17 Feb 2021 15:44:31
User entered 'Jennifer'	System	17 Feb 2021 15:44:16

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 16:28:09
DataPoint Verified.		13 Apr 2021 17:13:14
User signature succeeded.	Toby Briskin (b) (4)	12 Apr 2021 20:01:06
Un-reviewed for Safety.	(b) (4)	
System		12 Apr 2021 15:21:09
Signature has been broken.	System	12 Apr 2021 15:21:09
User entered 'Briskin'	System	12 Apr 2021 15:21:09
DataPoint Un-verified.	(b) (4), (b) (6)	01 Apr 2021 13:57:45
DataPoint Verified.		01 Apr 2021 13:57:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	17 Feb 2021 15:44:31
User entered 'Gaston'	System	17 Feb 2021 15:44:16

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

Site Address: [Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 16:28:09
DataPoint Verified.		13 Apr 2021 17:13:14
User signature succeeded.	Toby Briskin (b) (4)	12 Apr 2021 20:01:06
User entered '3619 Park East Drive, Suite 300'	(b) (4) System	12 Apr 2021 15:21:09

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

Site Address: [City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 16:28:09
DataPoint Verified.		13 Apr 2021 17:13:14
User signature succeeded.	Toby Briskin (b) (4)	12 Apr 2021 20:01:06
User entered 'Beachwood'	(b) (4) System	12 Apr 2021 15:21:09

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:57:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:44:31
User entered 'OH'	System	17 Feb 2021 15:44:16

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 16:28:09
DataPoint Verified.		13 Apr 2021 17:13:14
User signature succeeded.	Toby Briskin (b) (4)	12 Apr 2021 20:01:06
User entered '44122'	(b) (4) System	12 Apr 2021 15:21:09

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:57:41
Reviewed for Safety.		26 Mar 2021 19:18:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
User entered 'US'	(b) (4) System	17 Feb 2021 15:44:56

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	23 Apr 2021 14:26:39
User entered '4'	System	14 Apr 2021 16:27:32
User entered '3'	System	12 Apr 2021 15:21:09
User entered '2'	System	26 Mar 2021 19:19:04
User entered '1'	System	17 Feb 2021 15:44:56

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:38:18

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:13:14
User signature succeeded.	Toby Briskin (b) (4)	12 Apr 2021 20:01:06
	(b) (4)	
User entered '12/Apr/2021 15:21'	System	12 Apr 2021 15:21:09

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:38:18

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 16:28:09
DataPoint Verified.		13 Apr 2021 17:13:14
User signature succeeded.	Toby Briskin (b) (4)	12 Apr 2021 20:01:06
User entered 'I'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 15:21:09

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:57:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:44:31
User entered	System	17 Feb 2021 15:44:16
'USA-US075-2021-MRNA-1273-P301000006'		

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:57:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:44:31
User entered 'Yes (Y)'	System	17 Feb 2021 15:44:16

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:57:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:44:31
User entered 'No (N)'	System	17 Feb 2021 15:44:16

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:57:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:44:31
User entered 'No (N)'	System	17 Feb 2021 15:44:16

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:57:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:44:31
User entered 'No (N)'	System	17 Feb 2021 15:44:16

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:57:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:44:31
User entered 'No (N)'	System	17 Feb 2021 15:44:16

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:57:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:44:31
User entered 'No (N)'	System	17 Feb 2021 15:44:16

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:57:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:44:31
User entered 'Yes (Y)'	System	17 Feb 2021 15:44:16

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 16:28:09
DataPoint Verified.		13 Apr 2021 17:13:14
User signature succeeded.	Toby Briskin (b) (4)	12 Apr 2021 20:01:06
Un-reviewed for Safety.	(b) (4)	
System		12 Apr 2021 15:21:09
Signature has been broken.	System	12 Apr 2021 15:21:09
User entered 'Toby'	System	12 Apr 2021 15:21:09
DataPoint Un-verified.	(b) (4), (b) (6)	01 Apr 2021 13:57:43
DataPoint Verified.		01 Apr 2021 13:57:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	17 Feb 2021 15:44:31
User entered 'Jennifer'	System	17 Feb 2021 15:44:16

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 16:28:09
DataPoint Verified.		13 Apr 2021 17:13:14
User signature succeeded.	Toby Briskin (b) (4)	12 Apr 2021 20:01:06
Un-reviewed for Safety.	(b) (4)	
System		12 Apr 2021 15:21:09
Signature has been broken.	System	12 Apr 2021 15:21:09
User entered 'Briskin'	System	12 Apr 2021 15:21:09
DataPoint Un-verified.	(b) (4), (b) (6)	01 Apr 2021 13:57:45
DataPoint Verified.		01 Apr 2021 13:57:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	17 Feb 2021 15:44:31
User entered 'Gaston'	System	17 Feb 2021 15:44:16

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

Site Address: [Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 16:28:09
DataPoint Verified.		13 Apr 2021 17:13:14
User signature succeeded.	Toby Briskin (b) (4)	12 Apr 2021 20:01:06
User entered '3619 Park East Drive, Suite 300'	(b) (4) System	12 Apr 2021 15:21:09

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

Site Address: [City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 16:28:09
DataPoint Verified.		13 Apr 2021 17:13:14
User signature succeeded.	Toby Briskin (b) (4)	12 Apr 2021 20:01:06
User entered 'Beachwood'	(b) (4) System	12 Apr 2021 15:21:09

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:57:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:44:31
User entered 'OH'	System	17 Feb 2021 15:44:16

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 16:28:09
DataPoint Verified.		13 Apr 2021 17:13:14
User signature succeeded.	Toby Briskin (b) (4)	12 Apr 2021 20:01:06
User entered '44122'	(b) (4) System	12 Apr 2021 15:21:09

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:57:41
Reviewed for Safety.		26 Mar 2021 19:18:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
User entered 'US'	(b) (4) System	17 Feb 2021 15:44:56

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	23 Apr 2021 14:26:39
User entered '4'	System	14 Apr 2021 16:27:32
User entered '3'	System	12 Apr 2021 15:21:09
User entered '2'	System	26 Mar 2021 19:19:04
User entered '1'	System	17 Feb 2021 15:44:56

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:38:18

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Toby Briskin (b) (4)	14 Apr 2021 19:52:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:12:37
User entered '14/Apr/2021 12:27'	System	14 Apr 2021 16:27:32

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:38:18

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.	Toby Briskin (b) (4)	14 Apr 2021 19:52:16
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:37
Reviewed for Safety.		14 Apr 2021 16:28:09
User entered 'I'		14 Apr 2021 16:27:32

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:57:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:44:31
User entered	System	17 Feb 2021 15:44:16
'USA-US075-2021-MRNA-1273-P301000006'		

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:57:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:44:31
User entered 'Yes (Y)'	System	17 Feb 2021 15:44:16

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[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:57:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:44:31
User entered 'No (N)'	System	17 Feb 2021 15:44:16

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[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:57:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:44:31
User entered 'No (N)'	System	17 Feb 2021 15:44:16

US3182065

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:57:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:44:31
User entered 'No (N)'	System	17 Feb 2021 15:44:16

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Form: Safety Report Form

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:57:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:44:31
User entered 'No (N)'	System	17 Feb 2021 15:44:16

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Form: Safety Report Form

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:57:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:44:31
User entered 'No (N)'	System	17 Feb 2021 15:44:16

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Form: Safety Report Form

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:57:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:44:31
User entered 'Yes (Y)'	System	17 Feb 2021 15:44:16

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[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 16:28:09
DataPoint Verified.		13 Apr 2021 17:13:14
User signature succeeded.	Toby Briskin (b) (4)	12 Apr 2021 20:01:06
Un-reviewed for Safety.	(b) (4)	
System		12 Apr 2021 15:21:09
Signature has been broken.	System	12 Apr 2021 15:21:09
User entered 'Toby'	System	12 Apr 2021 15:21:09
DataPoint Un-verified.	(b) (4), (b) (6)	01 Apr 2021 13:57:43
DataPoint Verified.		01 Apr 2021 13:57:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	17 Feb 2021 15:44:31
User entered 'Jennifer'	System	17 Feb 2021 15:44:16

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Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 16:28:09
DataPoint Verified.		13 Apr 2021 17:13:14
User signature succeeded.	Toby Briskin (b) (4)	12 Apr 2021 20:01:06
Un-reviewed for Safety.	(b) (4)	
System		12 Apr 2021 15:21:09
Signature has been broken.	System	12 Apr 2021 15:21:09
User entered 'Briskin'	System	12 Apr 2021 15:21:09
DataPoint Un-verified.	(b) (4), (b) (6)	01 Apr 2021 13:57:45
DataPoint Verified.		01 Apr 2021 13:57:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	17 Feb 2021 15:44:31
User entered 'Gaston'	System	17 Feb 2021 15:44:16

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Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

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[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 16:28:09
DataPoint Verified.		13 Apr 2021 17:13:14
User signature succeeded.	Toby Briskin (b) (4)	12 Apr 2021 20:01:06
User entered '3619 Park East Drive, Suite 300'	(b) (4) System	12 Apr 2021 15:21:09

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Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

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Site Address: [City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 16:28:09
DataPoint Verified.		13 Apr 2021 17:13:14
User signature succeeded.	Toby Briskin (b) (4)	12 Apr 2021 20:01:06
User entered 'Beachwood'	(b) (4) System	12 Apr 2021 15:21:09

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Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

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[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:57:41
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:44:31
User entered 'OH'	System	17 Feb 2021 15:44:16

US3182065

Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

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[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	14 Apr 2021 16:28:09
DataPoint Verified.		13 Apr 2021 17:13:14
User signature succeeded.	Toby Briskin (b) (4)	12 Apr 2021 20:01:06
User entered '44122'	(b) (4) System	12 Apr 2021 15:21:09

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Form: Safety Report Form

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[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Apr 2021 13:57:41
Reviewed for Safety.		26 Mar 2021 19:18:14
User signature succeeded.	Mary Beth Manning	09 Mar 2021 04:07:04
User entered 'US'	(b) (4) System	17 Feb 2021 15:44:56

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Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:38:18

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	23 Apr 2021 14:26:39
User entered '4'	System	14 Apr 2021 16:27:32
User entered '3'	System	12 Apr 2021 15:21:09
User entered '2'	System	26 Mar 2021 19:19:04
User entered '1'	System	17 Feb 2021 15:44:56

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Folder: SAE USA-US075-2021-MRNA-1273-P301000006

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:38:18

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 12:28:32
User signature succeeded.	Mary Beth Manning	23 Apr 2021 15:17:48
	(b) (4)	
User entered '23/Apr/2021 09:26'	System	23 Apr 2021 14:26:39

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Form: Safety Report Form (5)

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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)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 12:28:32
User signature succeeded.	Mary Beth Manning	23 Apr 2021 15:17:48
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	23 Apr 2021 14:26:39