

US3352015 (Prod: Research Centers of America - ERG)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:10:26

All time stamps listed in this document are displayed in GMT

US3352015

Form: Participant Creation

Data signed: (b) (4) 26 Apr 2021 19:45:20

Generated On: 09 Jun 2021 17:10:26

Participant ID

US3352015

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

US3352015

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 19:45:22

Generated On: 09 Jun 2021 17:10:26

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

Visit date (dd MMM yyyy)	04 AUG 2020
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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	SCRN
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US3352015

Folder: Screening

Form: Demographics

Data signed: (b) (4) 26 Apr 2021 19:45:21

Generated On: 09 Jun 2021 17:10:26

Date of Birth (MMM yyyy)	(b) (6) 1979
Age	41
Age Units	YEARS
Age (Derived)	41
Sex	Female <input type="radio"/> Male <input checked="" 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

US3352015

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 26 Apr 2021 19:45:21

Generated On: 09 Jun 2021 17:10:26

Date of Informed Consent (*dd MMM yyyy*) 4 AUG 2020

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1	<input checked="" type="radio"/>
Amendment 2	<input type="radio"/>
Amendment 3	<input type="radio"/>
Amendment 4	<input type="radio"/>
Amendment 5	<input type="radio"/>

Was participant enrolled in the study?

Yes	<input checked="" type="radio"/>
No	<input type="radio"/>

If No, indicate reason for screen fail

Withdrew Consent	<input type="radio"/>
Inclusion/Exclusion	<input type="radio"/>
Cohort Full	<input type="radio"/>
Other	<input type="radio"/>

If reason for screen fail is Other, specify _____

Was this participant screened previously?

Yes	<input type="radio"/>
No	<input checked="" type="radio"/>

If Yes, previous participant number _____

Enrollment Trigger 1

US3352015

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 26 Apr 2021 19:45:21

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3352015

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 26 Apr 2021 19:45:22

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Were any significant conditions reported?

Yes ☒

No ☐

US3352015

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 26 Apr 2021 19:45:21

Generated On: 09 Jun 2021 17:10:26

Condition	ALLERGIC RHINITIS
Start date (dd MMM yyyy)	UN UNK 1983
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 1983
Start Year (derived)	1983
Stop Month and Year (derived)	
Stop Year (derived)	

US3352015

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 26 Apr 2021 19:45:21

Generated On: 09 Jun 2021 17:10:26

Condition	B-THALASSEMIA MINOR
Start date (dd MMM yyyy)	(b) (6) 1979
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)	(b) (6) 1979
Start Year (derived)	1979
Stop Month and Year (derived)	
Stop Year (derived)	

US3352015

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 26 Apr 2021 19:45:21

Generated On: 09 Jun 2021 17:10:26

Condition	L5-S1 DISC HERNIATION
Start date (dd MMM yyyy)	UN SEP 2011
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 SEP 2011
Stop date completely unknown	False
Start Month and Year (derived)	SEP 2011
Start Year (derived)	2011
Stop Month and Year (derived)	SEP 2011
Stop Year (derived)	2011

US3352015

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 26 Apr 2021 19:45:21

Generated On: 09 Jun 2021 17:10:26

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

US3352015

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 26 Apr 2021 19:45:21

Generated On: 09 Jun 2021 17:10:26

Condition	HEARTBURN
Start date (dd MMM yyyy)	06 JUN 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

US3352015

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 26 Apr 2021 19:45:21

Generated On: 09 Jun 2021 17:10:26

Condition	GALL-BLADDER STONES
Start date (dd MMM yyyy)	UN UNK 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	
Stop Year (derived)	

US3352015

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 26 Apr 2021 19:45:21

Generated On: 09 Jun 2021 17:10:26

Condition	FATTY LIVER
Start date (dd MMM yyyy)	UN UNK 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 26 Apr 2021 19:45:21

Generated On: 09 Jun 2021 17:10:26

Condition	ANXIETY
Start date (dd MMM yyyy)	01 JUN 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

US3352015

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 26 Apr 2021 19:45:21

Generated On: 09 Jun 2021 17:10:26

Condition	LAMINECTOMY
Start date (dd MMM yyyy)	UN SEP 2011
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 SEP 2011
Stop date completely unknown	False
Start Month and Year (derived)	SEP 2011
Start Year (derived)	2011
Stop Month and Year (derived)	SEP 2011
Stop Year (derived)	2011

US3352015

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 19:45:22

Generated On: 09 Jun 2021 17:10:26

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	4 AUG 2020
Time of assessment (00:00-23:59)	14:06 (24 HR)
Vital Signs Date and Time (derived)	4 AUG 2020 14:06
Height (xxx.x)	176.1 cm
Weight (xxx.x)	107.3 kg
BMI (xxx.x)	34.60039 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 19:45:22

Generated On: 09 Jun 2021 17:10:26

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

4 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 26 Apr 2021 19:45:22

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 26 Apr 2021 19:45:22

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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)	True
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 19:45:23

Generated On: 09 Jun 2021 17:10:26

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

Visit date (dd MMM yyyy)	4 AUG 2020
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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	VISIT1
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US3352015

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 26 Apr 2021 19:45:23

Generated On: 09 Jun 2021 17:10:26

What was the date of randomization? (dd MMM yyyy) 04 AUG 2020

What was the participant's randomization number? 101040

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) 26 Apr 2021 19:45:23

Generated On: 09 Jun 2021 17:10:26

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) 26 Apr 2021 19:45:23

Generated On: 09 Jun 2021 17:10:26

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)	4 AUG 2020
Time of assessment (00:00-23:59)	14:06 (24 HR)
Vital Signs Date and Time (derived)	4 AUG 2020 14:06
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)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3352015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Apr 2021 19:45:23

Generated On: 09 Jun 2021 17:10:26

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)	4 AUG 2020
Time of assessment (00:00-23:59)	16:56 (24 HR)
Vital Signs Date and Time (derived)	4 AUG 2020 16:56
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3352015

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 19:45:23

Generated On: 09 Jun 2021 17:10:26

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.

US3352015

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 26 Apr 2021 19:45:23

Generated On: 09 Jun 2021 17:10:26

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) 4 AUG 2020

What was the treatment time? (00:00-23:59) 16:26 (24 HR)

Treatment Date and Time (derived) 4 AUG 2020 16:26

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) 26 Apr 2021 19:45:23

Generated On: 09 Jun 2021 17:10:26

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

4 AUG 2020

Collection time (00:00-23:59)

15:30 (24 HR)

Collection date and time (derived)

4 AUG 2020 15:30

US3352015

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 26 Apr 2021 19:45:23

Generated On: 09 Jun 2021 17:10:26

Collection date (dd MMM yyyy)			4 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:17	4 AUG 2020 15:17
Nasopharyngeal Swab 2	No		

US3352015

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 19:45:23

Generated On: 09 Jun 2021 17:10:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 AUG 2020 17:00

PC Open Date & Time

04 AUG 2020 16:46

PC Close Date & Time

04 AUG 2020 19:16

US3352015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

PC Time Stamp	04 AUG 2020 20:15
PC Open Date & Time	04 AUG 2020 20:11
PC Close Date & Time	05 AUG 2020 11:59

US3352015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °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

05 AUG 2020 18:48

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3352015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:10:26

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

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

06 AUG 2020 18:44

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3352015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:10:26

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

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 AUG 2020 19:36

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3352015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 AUG 2020 15:12

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3352015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 AUG 2020 17:49

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3352015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:10:26

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

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

10 AUG 2020 16:50

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3352015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:10:26

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

04 AUG 2020 17:01

PC Open Date & Time

04 AUG 2020 16:46

PC Close Date & Time

04 AUG 2020 19:16

US3352015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:10:26

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

04 AUG 2020 20:15

PC Open Date & Time

04 AUG 2020 20:11

PC Close Date & Time

05 AUG 2020 11:59

US3352015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:10:26

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

05 AUG 2020 12:01

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3352015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:10:26

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

30

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

06 AUG 2020 18:44

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3352015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:10:26

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

07 AUG 2020 19:36

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3352015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:10:26

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

08 AUG 2020 15:12

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3352015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:10:26

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

09 AUG 2020 17:49

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3352015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:10:26

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

10 AUG 2020 16:50

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:26

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 ☐

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:26

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

No ☒

Yes ☐

PC Time stamp	04 AUG 2020 17:02
PC Open Date & Time	04 AUG 2020 16:46
PC Close Date & Time	04 AUG 2020 19:16

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:26

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 ☐

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:26

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

No ☒

Yes ☐

PC Time stamp	04 AUG 2020 20:16
PC Open Date & Time	04 AUG 2020 20:11
PC Close Date & Time	05 AUG 2020 11:59

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:26

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 ☒

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:26

Yes <input type="checkbox"/>	
PC Time stamp	05 AUG 2020 12:01
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:26

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 ☒

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:26

Yes <input type="checkbox"/>	
PC Time stamp	06 AUG 2020 18:45
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:26

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 ☒

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:26

Yes <input type="checkbox"/>	
PC Time stamp	07 AUG 2020 19:36
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:26

Yes <input type="checkbox"/>	
PC Time stamp	08 AUG 2020 15:12
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:26

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 ☒

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:26

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 17:49
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:26

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 ☒

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:26

Yes <input type="checkbox"/>	
PC Time stamp	10 AUG 2020 16:50
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3352015

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 19:45:21

Generated On: 09 Jun 2021 17:10:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3352015

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 19:45:21

Generated On: 09 Jun 2021 17:10:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352015

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 19:45:21

Generated On: 09 Jun 2021 17:10:26

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

US3352015

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 19:45:21

Generated On: 09 Jun 2021 17:10:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352015

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 19:45:21

Generated On: 09 Jun 2021 17:10:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3352015

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 19:45:21

Generated On: 09 Jun 2021 17:10:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352015

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 19:45:23

Generated On: 09 Jun 2021 17:10:26

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	3 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3352015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Apr 2021 19:45:23

Generated On: 09 Jun 2021 17:10:26

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)	3 SEP 2020
Time of assessment (00:00-23:59)	14:05 (24 HR)
Vital Signs Date and Time (derived)	3 SEP 2020 14:05
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	97 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3352015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Apr 2021 19:45:23

Generated On: 09 Jun 2021 17:10:26

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	3 SEP 2020
Time of assessment (00:00-23:59)	15:40 (24 HR)
Vital Signs Date and Time (derived)	3 SEP 2020 15:40
Temperature (xxx.x)	36.4 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3352015

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 19:45:23

Generated On: 09 Jun 2021 17:10:26

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.

US3352015

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 26 Apr 2021 19:45:23

Generated On: 09 Jun 2021 17:10:26

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) 3 SEP 2020

What was the treatment time? (00:00-23:59) 15:10 (24 HR)

Treatment Date and Time (derived) 3 SEP 2020 15:10

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

US3352015

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 19:45:23

Generated On: 09 Jun 2021 17:10:26

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

Collection date (dd MMM yyyy)	3 SEP 2020
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Collection time (00:00-23:59)	14:49 (24 HR)
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Collection date and time (derived)	3 SEP 2020 14:49
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US3352015

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 26 Apr 2021 19:45:23

Generated On: 09 Jun 2021 17:10:26

Collection date (dd MMM yyyy)			3 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:23	3 SEP 2020 14:23
Nasopharyngeal Swab 2	No		

US3352015

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 19:45:23

Generated On: 09 Jun 2021 17:10:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 15:43

PC Open Date & Time

03 SEP 2020 15:30

PC Close Date & Time

03 SEP 2020 18:00

US3352015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.8 °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 19:38
PC Open Date & Time	03 SEP 2020 18:55
PC Close Date & Time	04 SEP 2020 11:59

US3352015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.7 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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	04 SEP 2020 12:22
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3352015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:10:26

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

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 12:23

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3352015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:10:26

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

98.7 °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

06 SEP 2020 13:44

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3352015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

08 SEP 2020 07:03

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3352015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:10:26

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

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 22:07

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3352015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 12:21

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3352015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:10:26

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

03 SEP 2020 15:38

PC Open Date & Time

03 SEP 2020 15:30

PC Close Date & Time

03 SEP 2020 18:00

US3352015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:10:26

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

03 SEP 2020 19:38

PC Open Date & Time

03 SEP 2020 18:55

PC Close Date & Time

04 SEP 2020 11:59

US3352015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:10:26

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

40

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

04 SEP 2020 12:22

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3352015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:10:26

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 ☐

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

50

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)**

60

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

05 SEP 2020 12:24

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3352015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:10:26

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

06 SEP 2020 13:44

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3352015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:10:26

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

08 SEP 2020 07:04

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3352015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:10:26

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

08 SEP 2020 22:08

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3352015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:10:26

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

09 SEP 2020 12:21

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:26

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 ☐

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:26

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

No ☒

Yes ☐

PC Time stamp	03 SEP 2020 15:39
PC Open Date & Time	03 SEP 2020 15:30
PC Close Date & Time	03 SEP 2020 18:00

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:26

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 ☐

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:26

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

No ☒

Yes ☐

PC Time stamp	03 SEP 2020 19:38
PC Open Date & Time	03 SEP 2020 18:55
PC Close Date & Time	04 SEP 2020 11:59

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:26

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 ☐

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:26

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

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:26

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
EAB) (1725)

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US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:26

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 12:24
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:26

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

EAB) (1725)

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US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:26

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 13:44
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:26

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 ☒

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:26

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 07:04
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:26

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
EAB) (1725)

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US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:26

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 22:08
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:26

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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US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:26

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 12:21
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3352015

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 19:45:21

Generated On: 09 Jun 2021 17:10:26

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

US3352015

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 19:45:21

Generated On: 09 Jun 2021 17:10:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352015

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 19:45:21

Generated On: 09 Jun 2021 17:10:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3352015

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 19:45:21

Generated On: 09 Jun 2021 17:10:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352015

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 19:45:21

Generated On: 09 Jun 2021 17:10:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3352015

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 19:45:21

Generated On: 09 Jun 2021 17:10:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352015

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 19:45:23

Generated On: 09 Jun 2021 17:10:26

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	01 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3352015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 19:45:23

Generated On: 09 Jun 2021 17:10:26

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	01 OCT 2020
Time of assessment (00:00-23:59)	13:05 (24 HR)
Vital Signs Date and Time (derived)	01 OCT 2020 13:05
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3352015

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 19:45:23

Generated On: 09 Jun 2021 17:10:26

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.

US3352015

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 19:45:23

Generated On: 09 Jun 2021 17:10:26

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	01 OCT 2020
Collection time (00:00-23:59)	13:27 (24 HR)
Collection date and time (derived)	01 OCT 2020 13:27

US3352015

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 19:45:23

Generated On: 09 Jun 2021 17:10:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 OCT 2020 14:09:56
Patient Cloud Open Date & Time	04 OCT 2020 00:01
Patient Cloud Close Date & Time	08 OCT 2020 23:59

US3352015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 OCT 2020 12:08:38

Patient Cloud Open Date & Time

11 OCT 2020 00:01

Patient Cloud Close Date & Time

15 OCT 2020 23:59

US3352015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 OCT 2020 14:23:49

Patient Cloud Open Date & Time

18 OCT 2020 00:01

Patient Cloud Close Date & Time

22 OCT 2020 23:59

US3352015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 NOV 2020 01:09:58

Patient Cloud Open Date & Time

01 NOV 2020 00:01

Patient Cloud Close Date & Time

05 NOV 2020 23:59

US3352015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 NOV 2020 10:55:19
Patient Cloud Open Date & Time	08 NOV 2020 00:01
Patient Cloud Close Date & Time	12 NOV 2020 23:59

US3352015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

15 NOV 2020 00:01:36

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 NOV 2020 16:23:59
Patient Cloud Open Date & Time	19 NOV 2020 00:01
Patient Cloud Close Date & Time	23 NOV 2020 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

27 NOV 2020 16:39:42

Patient Cloud Open Date & Time

26 NOV 2020 00:01

Patient Cloud Close Date & Time

30 NOV 2020 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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	04 DEC 2020 11:23:09
Patient Cloud Open Date & Time	03 DEC 2020 00:01
Patient Cloud Close Date & Time	07 DEC 2020 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

10 DEC 2020 00:01:48

Patient Cloud Open Date & Time

10 DEC 2020 00:01

Patient Cloud Close Date & Time

14 DEC 2020 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

17 DEC 2020 00:41:48

Patient Cloud Open Date & Time

17 DEC 2020 00:01

Patient Cloud Close Date & Time

21 DEC 2020 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

26 DEC 2020 17:16:46

Patient Cloud Open Date & Time

24 DEC 2020 00:01

Patient Cloud Close Date & Time

28 DEC 2020 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

31 DEC 2020 00:12:25

Patient Cloud Open Date & Time

31 DEC 2020 00:01

Patient Cloud Close Date & Time

04 JAN 2021 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

07 JAN 2021 00:01:44

Patient Cloud Open Date & Time

07 JAN 2021 00:01

Patient Cloud Close Date & Time

11 JAN 2021 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 JAN 2021 08:22:36

Patient Cloud Open Date & Time

14 JAN 2021 00:01

Patient Cloud Close Date & Time

18 JAN 2021 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

21 JAN 2021 08:56:44

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

28 JAN 2021 00:01:37

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 FEB 2021 10:26:17

Patient Cloud Open Date & Time

04 FEB 2021 00:01

Patient Cloud Close Date & Time

08 FEB 2021 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 FEB 2021 07:55:50
Patient Cloud Open Date & Time	11 FEB 2021 00:01
Patient Cloud Close Date & Time	15 FEB 2021 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 FEB 2021 07:50:26

Patient Cloud Open Date & Time

18 FEB 2021 00:01

Patient Cloud Close Date & Time

22 FEB 2021 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 FEB 2021 15:46:56

Patient Cloud Open Date & Time

25 FEB 2021 00:01

Patient Cloud Close Date & Time

01 MAR 2021 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

04 MAR 2021 05:22:37

Patient Cloud Open Date & Time

04 MAR 2021 00:01

Patient Cloud Close Date & Time

08 MAR 2021 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

12 MAR 2021 22:51:27

Patient Cloud Open Date & Time

11 MAR 2021 00:01

Patient Cloud Close Date & Time

15 MAR 2021 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 MAR 2021 07:10:52

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 MAR 2021 00:50:46

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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 <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	01 APR 2021 00:03:00
Patient Cloud Open Date & Time	01 APR 2021 00:01
Patient Cloud Close Date & Time	05 APR 2021 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

08 APR 2021 14:07:24

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

15 APR 2021 19:20:44

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 APR 2021 12:50:48

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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"/>

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

[Patient Cloud Close Date & Time](#)

03 MAY 2021 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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 ☐

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

[Patient Cloud Open Date & Time](#)

06 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

[Patient Cloud Open Date & Time](#)

13 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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 ☐

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

[Patient Cloud Open Date & Time](#)

27 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

DAY 313

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

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

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

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

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

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

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

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

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

Date and time of submission	
Patient Cloud Open Date & Time	10 JUN 2021 00:01
Patient Cloud Close Date & Time	14 JUN 2021 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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"/>

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

[Patient Cloud Open Date & Time](#)

17 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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 ☐

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

[Patient Cloud Open Date & Time](#)

24 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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"/>

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

[Patient Cloud Open Date & Time](#)

01 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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"/>

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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"/>

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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 ☐

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

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 ☐

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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 ☐

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

[Patient Cloud Open Date & Time](#)

05 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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 ☐

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

[Patient Cloud Open Date & Time](#)

19 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	26 AUG 2021 00:01
Patient Cloud Close Date & Time	30 AUG 2021 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

[Patient Cloud Open Date & Time](#)

02 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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"/>

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

[Patient Cloud Open Date & Time](#)

09 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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="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"/>

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

[Patient Cloud Open Date & Time](#)

16 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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 ☐

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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 ☐

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

[Patient Cloud Open Date & Time](#)

07 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

Patient Cloud Open Date & Time	21 OCT 2021 00:01
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Patient Cloud Close Date & Time	25 OCT 2021 23:59
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US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

DAY 453

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

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

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

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

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

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

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

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

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

[Patient Cloud Open Date & Time](#)

28 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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"/>

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

[Patient Cloud Open Date & Time](#)

04 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

Patient Cloud Open Date & Time	11 NOV 2021 00:01
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Patient Cloud Close Date & Time	15 NOV 2021 23:59
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US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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 ☐

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

[Patient Cloud Open Date & Time](#)

18 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

DAY 481

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

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

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

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

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

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

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 ☐

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

[Patient Cloud Open Date & Time](#)

25 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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 ☐

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	02 DEC 2021 00:01
Patient Cloud Close Date & Time	06 DEC 2021 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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"/>

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

[Patient Cloud Open Date & Time](#)

09 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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°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 ☐

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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 ☐

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
Patient Cloud Close Date & Time	27 DEC 2021 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

DAY 516

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

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

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

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

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

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

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

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

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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 ☐

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

[Patient Cloud Open Date & Time](#)

06 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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 ☐

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 JAN 2022 00:01
Patient Cloud Close Date & Time	17 JAN 2022 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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 ☐

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

[Patient Cloud Open Date & Time](#)

20 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

DAY 544

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

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

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

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

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

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

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	27 JAN 2022 00:01
Patient Cloud Close Date & Time	31 JAN 2022 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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 ☐

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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 ☐

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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 ☐

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

[Patient Cloud Close Date & Time](#)

21 FEB 2022 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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 ☐

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

[Patient Cloud Open Date & Time](#)

03 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

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 ☐

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

[Patient Cloud Open Date & Time](#)

10 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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 ☐

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

[Patient Cloud Open Date & Time](#)

17 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

[Patient Cloud Open Date & Time](#)

24 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

[Patient Cloud Open Date & Time](#)

31 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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"/>

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

[Patient Cloud Open Date & Time](#)

14 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 APR 2022 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

[Patient Cloud Open Date & Time](#)

28 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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 ☐

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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 ☐

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

[Patient Cloud Open Date & Time](#)

26 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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"/>

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

[Patient Cloud Open Date & Time](#)

02 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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 ☐

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

DAY 684

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

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

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

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

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

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

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

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

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

[Patient Cloud Open Date & Time](#)

16 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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"/>

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

[Patient Cloud Open Date & Time](#)

23 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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 ☐

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

[Patient Cloud Open Date & Time](#)

07 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 JUL 2022 00:01
Patient Cloud Close Date & Time	18 JUL 2022 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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 ☐

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

[Patient Cloud Close Date & Time](#)

25 JUL 2022 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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"/>

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

[Patient Cloud Open Date & Time](#)

04 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

[Patient Cloud Open Date & Time](#)

11 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

[Patient Cloud Open Date & Time](#)

18 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

Patient Cloud Open Date & Time	25 AUG 2022 00:01
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Patient Cloud Close Date & Time	29 AUG 2022 23:59
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US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

[Patient Cloud Open Date & Time](#)

01 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

[Patient Cloud Open Date & Time](#)

08 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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 ☐

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

[Patient Cloud Open Date & Time](#)

15 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2022 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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 ☐

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

[Patient Cloud Open Date & Time](#)

29 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	06 OCT 2022 00:01
Patient Cloud Close Date & Time	10 OCT 2022 23:59

US3352015

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:10:26

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		04 MAR 2021 05:22:44

US3352015

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 19:45:21

Generated On: 09 Jun 2021 17:10:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3352015

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 19:45:21

Generated On: 09 Jun 2021 17:10:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352015

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 19:45:21

Generated On: 09 Jun 2021 17:10:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3352015

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 19:45:21

Generated On: 09 Jun 2021 17:10:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352015

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 19:45:21

Generated On: 09 Jun 2021 17:10:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3352015

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 19:45:21

Generated On: 09 Jun 2021 17:10:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352015

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 19:45:21

Generated On: 09 Jun 2021 17:10:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3352015

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 19:45:21

Generated On: 09 Jun 2021 17:10:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352015

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 19:45:23

Generated On: 09 Jun 2021 17:10:26

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

Visit date (dd MMM yyyy)	2 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3352015

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 19:45:23

Generated On: 09 Jun 2021 17:10:26

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3352015

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 19:45:23

Generated On: 09 Jun 2021 17:10:26

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.

US3352015

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 19:45:23

Generated On: 09 Jun 2021 17:10:26

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

Collection date (dd MMM yyyy)	2 MAR 2021
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Collection time (00:00-23:59)	13:27 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	2 MAR 2021 13:27
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US3352015

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 19:45:23

Generated On: 09 Jun 2021 17:10:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352015

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 19:45:21

Generated On: 09 Jun 2021 17:10:26

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

US3352015

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 19:45:21

Generated On: 09 Jun 2021 17:10:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352015

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:26

Was Contact Attempted?

Yes ☒

No ☐

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

3 MAY 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3352015

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352015

Folder: Safety Call Day 299 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:26

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

US3352015

Folder: Safety Call Day 299 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:26

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3352015

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:10:26

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"/>

US3352015

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:10:26

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3352015

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

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 19:45:20

Generated On: 09 Jun 2021 17:10:26

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

Visit date (dd MMM yyyy)	13 JAN 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3352015

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

Form: Unblinding

Data signed: (b) (4) 26 Apr 2021 19:45:20

Generated On: 09 Jun 2021 17:10:26

Date of updated informed consent (dd MMM yyyy) 13 JAN 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (dd MMM yyyy) 13 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3352015

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 19:45:20

Generated On: 09 Jun 2021 17:10:26

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

13 JAN 2021

Collection time (00:00-23:59)

10:33 (24 HR)

Collection date and time (derived)

13 JAN 2021 10:33

US3352015

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 26 Apr 2021 19:45:20

Generated On: 09 Jun 2021 17:10:26

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

Collection date (dd MMM yyyy)	13 JAN 2021
-------------------------------	-------------

Collection time (00:00 - 23:59)	10:47
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Collection Date and Time (derived)	13 JAN 2021 10:47
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US3352015

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 26 Apr 2021 19:45:20

Generated On: 09 Jun 2021 17:10:26

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3352015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:26

AEID	
Adverse event	RIGHT EARACHE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	04 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	04 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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EAB) (1725)

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US3352015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:26

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input 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 type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3352015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:26

AEID	USA-US066-2021-MRNA-1273-P30 1000009
Adverse event	ACUTE CHOLECYSTITIS
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)	21 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	28 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	26 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	28 MAR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:26

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

US3352015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:26

SUBJECT REPORTED HAVING
PAIN IN HIS UPPER RIGHT
QUADRANT IN HIS ABDOMEN
AND DECIDED TO GO TO
SOUTH MIAMI HOSPITAL ON
26MAR2021. HE HAD ACUTE
CHOLECYSTITIS AND WAS
HOSPITALIZED. ON 27MAR2021
IN THE MORNING HE HAD A
CHOLECYSTECTOMY. SUBJECT
WAS DISCHARGED ON
28MAR2021.

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

US3352015

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:26

AEID	
Adverse event	NAUSEA
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)	25 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	28 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:26

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

US3352015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:26

AEID	
Adverse event	HEPATOMEGALY
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)	26 APR 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 checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:26

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

US3352015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:26

AEID	
Adverse event	LEUKOCYTOSIS
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	26 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	27 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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US3352015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:26

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

US3352015

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:10:26

AEID	
Adverse event	HEPATIC STEATOSIS
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	26 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:10:26

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

US3352015

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:10:26

AEID	
Adverse event	UMBILICAL HERNIA
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)	26 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	27 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:10:26

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

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 26 Apr 2021 19:45:20

Generated On: 09 Jun 2021 17:10:26

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

Yes ☒

No ☐

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

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 19:45:20

Generated On: 09 Jun 2021 17:10:26

Name of Medication PROTONIX (GENERIC:
PANTOPRAZOLE)

Prophylaxis Yes ☐
No ☒

Indication HEARTBURN

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 19:45:20

Generated On: 09 Jun 2021 17:10:26

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		06 JUN 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"/>

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 19:45:20

Generated On: 09 Jun 2021 17:10:26

Name of Medication SERTRALINE

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 19:45:20

Generated On: 09 Jun 2021 17:10:26

	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)	01 JUN 2019	
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"/>

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 19:45:20

Generated On: 09 Jun 2021 17:10:26

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication EARACHE

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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 19:45:20

Generated On: 09 Jun 2021 17:10:26

	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)		04 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 04 SEP 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"/>

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 19:45:20

Generated On: 09 Jun 2021 17:10:26

Name of Medication TORADOL

Prophylaxis Yes ☐
No ☒

Indication ACUTE CHOLECYSTECTOMY

Dose per administration 15

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 19:45:20

Generated On: 09 Jun 2021 17:10:26

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 checked="" 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)	26 MAR 2021
Start date completely unknown	False
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>

If not Ongoing, End date (dd MMM yyyy)	28 MAR 2021
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"/>

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 19:45:20

Generated On: 09 Jun 2021 17:10:26

Name of Medication PERCOCET

Prophylaxis Yes ☐
No ☒

Indication ABDOMINAL PAIN

Dose per administration 5/325

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY 6 HOURS
AS NEEDED

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 19:45:20

Generated On: 09 Jun 2021 17:10:26

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	26 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		29 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 19:45:20

Generated On: 09 Jun 2021 17:10:26

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication ABDOMINAL PAIN

Dose per administration 650

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY 6 HOURS AS NEEDED

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 19:45:20

Generated On: 09 Jun 2021 17:10:26

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

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Apr 2021 19:45:20

Generated On: 09 Jun 2021 17:10:26

Name of Medication COLACE

Prophylaxis Yes ☐
No ☒

Indication ABDOMINAL PAIN

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Apr 2021 19:45:20

Generated On: 09 Jun 2021 17:10:26

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	26 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	28 MAR 2021	
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input checked="" type="radio"/>	

US3352015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 26 Apr 2021 19:45:20

Generated On: 09 Jun 2021 17:10:26

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3352015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 26 Apr 2021 19:45:20

Generated On: 09 Jun 2021 17:10:26

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
27 MAR 2021	CHOLECYSTECTOMY	Adverse Event	
26 MAR 2021	RIGHT UPPER QUADRANT ULTRASOUND	Adverse Event	
26 MAR 2021	SARS COV 2 (COVID 19)	Diagnostic	
26 MAR 2021	EKG	Diagnostic	

US3352015

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:10:26

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

US3352015

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:10:26

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 ☐

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

SAEID	USA-US066-2021-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	SURISADAY
Investigator's Last Name	MEDEROS
Site Address: Street	9299 SW 152 ST
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33031
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:10:26

SAEID	USA-US066-2021-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	SURISADAY
Investigator's Last Name	MEDEROS
Site Address: Street	9299 SW 152 ST
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33031
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	30/MAR/2021 08:13
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

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:10:26

SAEID	USA-US066-2021-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	SURISADAY
Investigator's Last Name	MEDEROS
Site Address: Street	9299 SW 152 ST
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33031
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	08/APR/2021 13:25
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

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:10:26

SAEID	USA-US066-2021-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	SURISADAY
Investigator's Last Name	MEDEROS
Site Address: Street	9299 SW 152 ST
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33031
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	12/APR/2021 13:08
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:10:26

SAEID	USA-US066-2021-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	SURISADAY
Investigator's Last Name	MEDEROS
Site Address: Street	9299 SW 152 ST
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33031
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	19/APR/2021 13:29
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:10:26

SAEID	USA-US066-2021-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	SURISADAY
Investigator's Last Name	MEDEROS
Site Address: Street	9299 SW 152 ST
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33031
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	19/APR/2021 19:30
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

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:10:26

SAEID	USA-US066-2021-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	SURISADAY
Investigator's Last Name	MEDEROS
Site Address: Street	9299 SW 152 ST
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33031
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	28/APR/2021 09:57
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

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 17:10:26

SAEID	USA-US066-2021-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	SURISADAY
Investigator's Last Name	MEDEROS
Site Address: Street	9299 SW 152 ST
Site Address: City	MIAMI
Site Address: State	FL
Site Address: Postal Code	33031
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	30/APR/2021 10:06
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

US3352015 (Prod: Research Centers of America - ERG)

US3352015

Form: Participant Creation

Generated On: 09 Jun 2021 17:10:26

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'US3352015'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 18:54:15

US3352015

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:10:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Aug 2020 15:46:40

US3352015

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '04 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 18:54:15

US3352015

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	06 Aug 2020 15:46:40

US3352015

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:10:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User entered 'SCRN'	System	06 Aug 2020 15:46:40

US3352015

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:10:26

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered (b) (6) 1979'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 18:54:16

US3352015

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:10:26

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '41'	(b) (4), (b) (6)	06 Aug 2020 15:47:18

US3352015

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:10:26

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User entered 'YEARS'	System	06 Aug 2020 15:47:18

US3352015

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:10:26

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User entered '41'	System	04 Aug 2020 20:42:22

US3352015

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:10:26

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Male (M)'	(b) (4), (b) (6)	06 Aug 2020 15:47:18

US3352015

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:10:26

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	06 Aug 2020 15:47:18

US3352015

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:10:26

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'I'	(b) (4), (b) (6)	06 Aug 2020 15:47:18

US3352015

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:10:26

Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 15:47:18

US3352015

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:10:26

Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 15:47:18

US3352015

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:10:26

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 15:47:18

US3352015

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:10:26

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 15:47:18

US3352015

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:10:26

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 15:47:18

US3352015

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:10:26

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 15:47:18

US3352015

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:10:26

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 15:47:18

US3352015

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:10:26

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 15:47:18

US3352015

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:10:26

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '4 Aug 2020'	(b) (4), (b) (6)	04 Aug 2020 20:42:22

US3352015

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User entered 'Aug 2020'	System	04 Aug 2020 20:42:22

US3352015

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User entered '2020'	System	04 Aug 2020 20:42:22

US3352015

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:10:26

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Amendment 1 (1)'	(b) (4), (b) (6)	04 Aug 2020 20:42:22

US3352015

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Aug 2020 20:42:22

US3352015

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:10:26

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered empty.	(b) (4), (b) (6)	04 Aug 2020 20:42:22

US3352015

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:10:26

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered empty.	(b) (4), (b) (6)	04 Aug 2020 20:42:22

US3352015

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:10:26

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'No (N)'	(b) (4), (b) (6)	04 Aug 2020 20:42:22

US3352015

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:10:26

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 18:54:15

US3352015

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:10:26

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User entered 'I'	System	04 Aug 2020 20:44:45

US3352015

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Aug 2020 20:44:45

US3352015

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:10:26

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Aug 2020 15:47:40

US3352015

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:10:26

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Upper respiratory tract disorders (excl infections), HLT: Nasal congestion and inflammations, PT: Rhinitis allergic, LLT: Allergic rhinitis - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 15:50:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 15:50:14
Data point term sent to Coder	System	06 Aug 2020 15:49:03
User entered 'ALLERGIC RHINITIS'	(b) (4), (b) (6)	06 Aug 2020 15:48:11

US3352015

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'UN UNK 1983'	(b) (4), (b) (6)	06 Aug 2020 15:48:11

US3352015

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:10:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 15:48:11

US3352015

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:10:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Aug 2020 15:48:11

US3352015

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 15:48:11

US3352015

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:10:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 15:48:11

US3352015

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:10:26

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User entered 'Jan 1983'	System	06 Aug 2020 15:48:11

US3352015

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User entered '1983'	System	06 Aug 2020 15:48:11

US3352015

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User entered empty.	System	06 Aug 2020 15:48:11

US3352015

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User entered empty.	System	06 Aug 2020 15:48:11

US3352015

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:10:26

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User coded data point as SOC: Congenital, familial and genetic disorders, HLGT: Blood and lymphatic system disorders congenital, HLT: Haemoglobinopathies congenital, PT: Thalassaemia minor, LLT: Thalassemia minor - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 18:52:29
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 18:52:29
Data point term sent to Coder	System	06 Aug 2020 15:53:12
User entered 'B-THALASSEMIA MINOR'	(b) (4), (b) (6)	06 Aug 2020 15:52:23

US3352015

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:10:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User closed query 'Start date is prior to Date of Birth. System Please correct.' (Site from System).		06 Aug 2020 15:55:23
User entered (b) (6) 1979' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Aug 2020 15:55:23
User opened query 'Start date is prior to Date of Birth. Please correct.' (Site from System).	System	06 Aug 2020 15:52:23
User entered (b) (6) 1979'	(b) (4), (b) (6)	06 Aug 2020 15:52:23

US3352015

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:10:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 15:52:23

US3352015

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:10:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Aug 2020 15:52:23

US3352015

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 15:52:23

US3352015

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:10:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 15:52:23

US3352015

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User entered (b) (6) 1979'	System	06 Aug 2020 15:55:23
User entered 'Jan 1979'	System	06 Aug 2020 15:52:23

US3352015

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User entered '1979'	System	06 Aug 2020 15:52:23

US3352015

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User entered empty.	System	06 Aug 2020 15:52:23

US3352015

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User entered empty.	System	06 Aug 2020 15:52:23

US3352015

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:10:26

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc protrusion, LLT: Intervertebral disc herniation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Aug 2020 00:17:30
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Aug 2020 00:17:30
Data point term sent to Coder	System	06 Aug 2020 15:53:15
User entered 'L5-S1 DISC HERNIATION'	(b) (4), (b) (6)	06 Aug 2020 15:52:55

US3352015

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'UN Sep 2011'	(b) (4), (b) (6)	06 Aug 2020 15:52:55

US3352015

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:10:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 15:52:55

US3352015

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:10:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 15:52:55

US3352015

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'UN Sep 2011'	(b) (4), (b) (6)	06 Aug 2020 15:52:55

US3352015

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:10:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 15:52:55

US3352015

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User entered 'Sep 2011'	System	06 Aug 2020 15:52:55

US3352015

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User entered '2011'	System	06 Aug 2020 15:52:55

US3352015

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User entered 'Sep 2011'	System	06 Aug 2020 15:52:55

US3352015

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User entered '2011'	System	06 Aug 2020 15:52:55

US3352015

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:10:26

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Sleep apnea - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Aug 2020 15:54:09
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 15:54:09
Data point term sent to Coder	System	06 Aug 2020 15:53:15
User entered 'SLEEP APNEA'	(b) (4), (b) (6)	06 Aug 2020 15:53:10

US3352015

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'UN UNK 2017'	(b) (4), (b) (6)	06 Aug 2020 15:53:10

US3352015

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:10:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 15:53:10

US3352015

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:10:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Aug 2020 15:53:10

US3352015

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 15:53:10

US3352015

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:10:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 15:53:10

US3352015

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User entered 'Jan 2017'	System	06 Aug 2020 15:53:10

US3352015

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User entered '2017'	System	06 Aug 2020 15:53:10

US3352015

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User entered empty.	System	06 Aug 2020 15:53:10

US3352015

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User entered empty.	System	06 Aug 2020 15:53:10

US3352015

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:10:26

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Dyspeptic signs and symptoms, PT: Dyspepsia, LLT: Heartburn - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 15:55:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 15:55:24
Data point term sent to Coder	System	06 Aug 2020 15:54:16
User entered 'HEARTBURN'	(b) (4), (b) (6)	06 Aug 2020 15:53:39

US3352015

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '06 Jun 2020'	(b) (4), (b) (6)	06 Aug 2020 15:53:39

US3352015

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:10:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 15:53:39

US3352015

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:10:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Aug 2020 15:53:39

US3352015

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 15:53:39

US3352015

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:10:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 15:53:39

US3352015

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:10:26

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User entered 'Jun 2020'	System	06 Aug 2020 15:53:39

US3352015

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User entered '2020'	System	06 Aug 2020 15:53:39

US3352015

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User entered empty.	System	06 Aug 2020 15:53:39

US3352015

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User entered empty.	System	06 Aug 2020 15:53:39

US3352015

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:10:26

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholelithiasis, LLT: Gallbladder stones - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 22:35:25
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 22:35:25
Data point term sent to Coder	System	06 Aug 2020 15:54:16
User entered 'GALL-BLADDER STONES'	(b) (4), (b) (6)	06 Aug 2020 15:54:05

US3352015

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'UN UNK 2016'	(b) (4), (b) (6)	06 Aug 2020 15:54:05

US3352015

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:10:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 15:54:05

US3352015

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:10:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Aug 2020 15:54:05

US3352015

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 15:54:05

US3352015

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:10:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 15:54:05

US3352015

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:10:26

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User entered 'Jan 2016'	System	06 Aug 2020 15:54:05

US3352015

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User entered '2016'	System	06 Aug 2020 15:54:05

US3352015

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User entered empty.	System	06 Aug 2020 15:54:05

US3352015

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User entered empty.	System	06 Aug 2020 15:54:05

US3352015

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:10:26

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User coded data point as SOC: Hepatobiliary disorders, HLGT: Hepatic and hepatobiliary disorders, HLT: Hepatocellular damage and hepatitis NEC, PT: Hepatic steatosis, LLT: Fatty liver - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 15:56:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 15:56:08
Data point term sent to Coder	System	06 Aug 2020 15:55:18
User entered 'FATTY LIVER'	(b) (4), (b) (6)	06 Aug 2020 15:54:30

US3352015

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'UN UNK 2016'	(b) (4), (b) (6)	06 Aug 2020 15:54:30

US3352015

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:10:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 15:54:30

US3352015

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:10:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Aug 2020 15:54:30

US3352015

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 15:54:30

US3352015

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:10:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 15:54:30

US3352015

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User entered 'Jan 2016'	System	06 Aug 2020 15:54:30

US3352015

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:10:26

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User entered '2016'	System	06 Aug 2020 15:54:30

US3352015

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User entered empty.	System	06 Aug 2020 15:54:30

US3352015

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User entered empty.	System	06 Aug 2020 15:54:30

US3352015

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:10:26

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 15:56:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 15:56:09
Data point term sent to Coder	System	06 Aug 2020 15:55:18
User entered 'ANXIETY'	(b) (4), (b) (6)	06 Aug 2020 15:54:57

US3352015

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '01 Jun 2019'	(b) (4), (b) (6)	06 Aug 2020 15:54:57

US3352015

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:10:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 15:54:57

US3352015

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:10:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Aug 2020 15:54:57

US3352015

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 15:54:57

US3352015

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:10:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 15:54:57

US3352015

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:10:26

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User entered 'Jun 2019'	System	06 Aug 2020 15:54:57

US3352015

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:10:26

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User entered '2019'	System	06 Aug 2020 15:54:57

US3352015

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User entered empty.	System	06 Aug 2020 15:54:57

US3352015

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User entered empty.	System	06 Aug 2020 15:54:57

US3352015

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:10:26

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Spine and spinal cord therapeutic procedures, PT: Spinal laminectomy, LLT: Spinal laminectomy - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 15:58:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 15:58:23
Data point term sent to Coder	System	06 Aug 2020 15:57:20
User entered 'LAMINECTOMY'	(b) (4), (b) (6)	06 Aug 2020 15:56:23

US3352015

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'UN Sep 2011'	(b) (4), (b) (6)	06 Aug 2020 15:56:23

US3352015

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:10:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 15:56:23

US3352015

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:10:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 15:56:23

US3352015

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'UN Sep 2011'	(b) (4), (b) (6)	06 Aug 2020 15:56:23

US3352015

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:10:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 15:56:23

US3352015

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:10:26

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User entered 'Sep 2011'	System	06 Aug 2020 15:56:23

US3352015

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User entered '2011'	System	06 Aug 2020 15:56:23

US3352015

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User entered 'Sep 2011'	System	06 Aug 2020 15:56:23

US3352015

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User entered '2011'	System	06 Aug 2020 15:56:23

US3352015

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Aug 2020 15:57:44

US3352015

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '4 Aug 2020'	(b) (4), (b) (6)	06 Aug 2020 15:57:44

US3352015

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '14:06'	(b) (4), (b) (6)	06 Aug 2020 15:57:44

US3352015

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User entered '4 Aug 2020 14:06'	System	06 Aug 2020 15:57:44

US3352015

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:26

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '176.1' cm reason for change: Data Entry Error	(b) (4), (b) (6)	06 Aug 2020 16:00:33
User entered missing code ND - Not Done.	(b) (4), (b) (6)	06 Aug 2020 15:57:44
DataPoint set to visible.	System	04 Aug 2020 20:44:45

US3352015

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:26

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '107.3' kg reason for change: Data Entry Error	(b) (4), (b) (6)	06 Aug 2020 16:00:33
User entered missing code ND - Not Done.	(b) (4), (b) (6)	06 Aug 2020 15:57:44
DataPoint set to visible.	System	04 Aug 2020 20:44:45

US3352015

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:26

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
Amendment Manager: User entered '34.60039'	System	16 Sep 2020 23:42:56
User entered '34.6'	System	06 Aug 2020 16:00:33
User entered empty.	System	06 Aug 2020 15:57:44
DataPoint set to visible.	System	04 Aug 2020 20:44:45

US3352015

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:26

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User entered 'kg/m2'	System	06 Aug 2020 16:00:33
User entered empty.	System	06 Aug 2020 15:57:44
DataPoint set to visible.	System	04 Aug 2020 20:44:45

US3352015

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered missing code ND - Not Done.	(b) (4), (b) (6)	06 Aug 2020 15:57:44

US3352015

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Oral (Oral)'	(b) (4), (b) (6)	06 Aug 2020 15:57:44

US3352015

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 15:57:44

US3352015

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered missing code ND - Not Done.	(b) (4), (b) (6)	06 Aug 2020 15:57:44

US3352015

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User entered 'bpm'	System	06 Aug 2020 15:57:44

US3352015

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered missing code ND - Not Done.	(b) (4), (b) (6)	06 Aug 2020 15:57:44

US3352015

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User entered 'breaths/min'	System	06 Aug 2020 15:57:44

US3352015

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered missing code ND - Not Done.	(b) (4), (b) (6)	06 Aug 2020 15:57:44

US3352015

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User entered 'mmHg'	System	06 Aug 2020 15:57:44

US3352015

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered missing code ND - Not Done.	(b) (4), (b) (6)	06 Aug 2020 15:57:44

US3352015

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User entered 'mmHg'	System	06 Aug 2020 15:57:44

US3352015

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:26

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29

US3352015

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:26

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29

US3352015

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:10:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Aug 2020 15:57:56

US3352015

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:10:26

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	07 Sep 2020 10:54:33
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	03 Sep 2020 20:43:36
User entered '4 Aug 2020'	(b) (4), (b) (6)	06 Aug 2020 15:57:56

US3352015

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 15:58:33

US3352015

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 15:58:33

US3352015

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:26

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)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 15:58:33

US3352015

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:26

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)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 15:58:33

US3352015

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:26

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 15:58:33

US3352015

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:26

[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)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 15:58:33

US3352015

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:26

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)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 15:58:33

US3352015

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:26

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)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 15:58:33

US3352015

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:26

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)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 15:58:33

US3352015

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:26

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)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 15:58:33

US3352015

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:26

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)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Aug 2020 15:58:33

US3352015

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:26

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 15:58:33

US3352015

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:26

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 15:58:33

US3352015

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:26

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 15:58:33

US3352015

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:26

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 15:58:33

US3352015

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:26

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)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 15:58:33

US3352015

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:26

[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)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 15:58:33

US3352015

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:26

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)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 15:58:33

US3352015

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'I'	(b) (4), (b) (6)	06 Aug 2020 15:58:33

US3352015

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:26

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 15:58:33

US3352015

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:10:26

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 15:58:33

US3352015

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:10:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:34
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Aug 2020 15:59:00

US3352015

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:34
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '4 Aug 2020'	(b) (4), (b) (6)	06 Aug 2020 15:59:00

US3352015

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:34
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	06 Aug 2020 15:59:00

US3352015

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:10:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:34
User entered 'VISIT1'	System	06 Aug 2020 15:59:00

US3352015

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:34
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '04 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 19:44:28

US3352015

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:10:26

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:34
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 02:03:28
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:03:28
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	04 Aug 2020 19:44:28
User entered '101040' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 19:44:28

US3352015

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:34
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 19:44:28

US3352015

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:10:26

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)	30 Apr 2021 07:18:34
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 15:59:28

US3352015

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:10:26

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)	30 Apr 2021 07:18:34
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 15:59:28

US3352015

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:34
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 15:59:28

US3352015

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:10:26

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:34
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 15:59:28

US3352015

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:10:26

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:34
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 15:59:28

US3352015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:10:26

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:34
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered missing code ND - Not Done.	(b) (4), (b) (6)	06 Aug 2020 16:03:09

US3352015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:10:26

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:34
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered missing code ND - Not Done.	(b) (4), (b) (6)	06 Aug 2020 16:03:09

US3352015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:10:26

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:34
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered missing code ND - Not Done.	(b) (4), (b) (6)	06 Aug 2020 16:03:09

US3352015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:10:26

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:34
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered missing code ND - Not Done.	(b) (4), (b) (6)	06 Aug 2020 16:03:09

US3352015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:26

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:34
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	06 Aug 2020 16:03:09

US3352015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:26

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:34
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Aug 2020 16:03:09

US3352015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:34
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '4 Aug 2020'	(b) (4), (b) (6)	06 Aug 2020 16:03:09

US3352015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:34
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '14:06'	(b) (4), (b) (6)	06 Aug 2020 16:03:09

US3352015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:34
User entered '4 Aug 2020 14:06'	System	06 Aug 2020 16:03:09

US3352015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:34
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '98.2' F	(b) (4), (b) (6)	06 Aug 2020 16:03:09

US3352015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:34
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Oral (Oral)'	(b) (4), (b) (6)	06 Aug 2020 16:03:09

US3352015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:34
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 16:03:09

US3352015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:34
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '76'	(b) (4), (b) (6)	06 Aug 2020 16:03:09

US3352015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:34
User entered 'bpm'	System	06 Aug 2020 16:03:09

US3352015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:34
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '15'	(b) (4), (b) (6)	06 Aug 2020 16:03:09

US3352015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:34
User entered 'breaths/min'	System	06 Aug 2020 16:03:09

US3352015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:34
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '115'	(b) (4), (b) (6)	06 Aug 2020 16:03:09

US3352015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:34
User entered 'mmHg'	System	06 Aug 2020 16:03:09

US3352015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:34
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '74'	(b) (4), (b) (6)	06 Aug 2020 16:03:09

US3352015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:34
User entered 'mmHg'	System	06 Aug 2020 16:03:09

US3352015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:10:26

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:34
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered missing code ND - Not Done.	(b) (4), (b) (6)	06 Aug 2020 16:03:09

US3352015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:10:26

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:34
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered missing code ND - Not Done.	(b) (4), (b) (6)	06 Aug 2020 16:03:09

US3352015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:26

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:34
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	06 Aug 2020 16:03:09

US3352015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:26

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:34
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Aug 2020 16:03:09

US3352015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:34
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '4 Aug 2020'	(b) (4), (b) (6)	06 Aug 2020 16:03:09

US3352015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:34
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	10 Aug 2020 10:42:58
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'POST-DOSE WAS COMPLETED 30 MIN AS PER PROTOCOL' (Site from System).	(b) (4), (b) (6)	06 Aug 2020 16:03:17
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).		06 Aug 2020 16:03:09
User entered '16:56'	(b) (4), (b) (6)	06 Aug 2020 16:03:09

US3352015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:34
User entered '4 Aug 2020 16:56'	System	06 Aug 2020 16:03:09

US3352015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:34
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '36.8' C	(b) (4), (b) (6)	06 Aug 2020 16:03:09

US3352015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:34
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Oral (Oral)'	(b) (4), (b) (6)	06 Aug 2020 16:03:09

US3352015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:34
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 16:03:09

US3352015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:34
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '59'	(b) (4), (b) (6)	06 Aug 2020 16:03:09

US3352015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:34
User entered 'bpm'	System	06 Aug 2020 16:03:09

US3352015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:34
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '14'	(b) (4), (b) (6)	06 Aug 2020 16:03:09

US3352015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:34
User entered 'breaths/min'	System	06 Aug 2020 16:03:09

US3352015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:34
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '116'	(b) (4), (b) (6)	06 Aug 2020 16:03:09

US3352015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:34
User entered 'mmHg'	System	06 Aug 2020 16:03:09

US3352015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:34
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '75'	(b) (4), (b) (6)	06 Aug 2020 16:03:09

US3352015

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:34
User entered 'mmHg'	System	06 Aug 2020 16:03:09

US3352015

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:10:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:34
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 16:03:26

US3352015

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:10:26

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:34
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 16:03:26

US3352015

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:10:26

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:34
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Aug 2020 20:45:19

US3352015

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:10:26

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:34
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered empty.	(b) (4), (b) (6)	04 Aug 2020 20:45:19

US3352015

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:10:26

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)	30 Apr 2021 07:18:34
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered empty.	(b) (4), (b) (6)	04 Aug 2020 20:45:19

US3352015

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:10:26

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:34
User entered 'MRNA-1273 OR PLACEBO'	System	04 Aug 2020 20:45:19

US3352015

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:10:26

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:34
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '4 Aug 2020'	(b) (4), (b) (6)	04 Aug 2020 20:45:19

US3352015

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:34
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '16:26'	(b) (4), (b) (6)	04 Aug 2020 20:45:19

US3352015

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:34
User entered '4 Aug 2020 16:26'	System	04 Aug 2020 20:45:19

US3352015

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:34
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	04 Aug 2020 20:45:19

US3352015

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:10:26

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:34
User entered 'ONCE'	System	04 Aug 2020 20:45:19

US3352015

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:10:26

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:34
User entered 'INTRAMUSCULAR'	System	04 Aug 2020 20:45:19

US3352015

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:34
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Aug 2020 16:03:50

US3352015

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:26

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:34
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '4 Aug 2020'	(b) (4), (b) (6)	06 Aug 2020 16:03:50

US3352015

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:26

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:34
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '15:30'	(b) (4), (b) (6)	06 Aug 2020 16:03:50

US3352015

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:26

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:34
User entered '4 Aug 2020 15:30'	System	06 Aug 2020 16:03:50

US3352015

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:10:26

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:34
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '4 Aug 2020'	(b) (4), (b) (6)	06 Aug 2020 16:04:08

US3352015

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:10:26

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:34
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	06 Aug 2020 16:04:08

US3352015

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:10:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:34
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Aug 2020 16:04:08

US3352015

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:10:26

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:34
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '15:17'	(b) (4), (b) (6)	06 Aug 2020 16:04:08

US3352015

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:10:26

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:34
User entered '4 Aug 2020 15:17'	System	06 Aug 2020 16:04:08

US3352015

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:10:26

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:34
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	06 Aug 2020 16:04:08

US3352015

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:10:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:34
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 16:04:08

US3352015

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:10:26

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:34
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 16:04:08

US3352015

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:10:26

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:34
User entered empty.	System	06 Aug 2020 16:04:08

US3352015

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:34
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Aug 2020 16:04:21

US3352015

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:10:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:18:34
User entered 'I'	System	06 Aug 2020 16:04:21

US3352015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
Data entry locked.	System	04 Aug 2020 20:45:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Aug 2020 20:45:19

US3352015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:10:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-04T16:59:32', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '5689c9a0-9e1f-4c0b-8b19-2f4bc059f928' User entered 'Yes (Y)'	System	04 Aug 2020 21:00:50
	System	04 Aug 2020 21:00:50

US3352015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:10:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-04T17:00:33', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '5689c9a0-9e1f-4c0b-8b19-2f4bc059f928' User entered '97.4'	System	04 Aug 2020 21:00:50
	System	04 Aug 2020 21:00:50

US3352015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-04T17:00:38', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '5689c9a0-9e1f-4c0b-8b19-2f4bc059f928'	System	04 Aug 2020 21:00:50
User entered 'No (N)'	System	04 Aug 2020 21:00:50

US3352015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:10:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-04T17:00:42', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '5689c9a0-9e1f-4c0b-8b19-2f4bc059f928'	System	04 Aug 2020 21:00:50
User entered '04 Aug 2020 17:00'	System	04 Aug 2020 21:00:50

US3352015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:10:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '04 Aug 2020 16:46'	System	04 Aug 2020 20:45:19

US3352015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:10:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '04 Aug 2020 19:16'	System	04 Aug 2020 20:45:19

US3352015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
Data entry locked.	System	04 Aug 2020 20:45:19
User entered 'Day 1, after vaccination (at home)'	System	04 Aug 2020 20:45:19

US3352015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:10:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-04T20:15:00', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'bbc6bc24-a9d9-4f28-b592-cfa9af8262e0' User entered 'Yes (Y)'	System	05 Aug 2020 00:15:20
	System	05 Aug 2020 00:15:20

US3352015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:10:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-04T20:15:06', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'bbc6bc24-a9d9-4f28-b592-cfa9af8262e0' User entered '98.0'	System	05 Aug 2020 00:15:20
	System	05 Aug 2020 00:15:20

US3352015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-04T20:15:12', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'bbc6bc24-a9d9-4f28-b592-cfa9af8262e0' User entered 'No (N)'	System	05 Aug 2020 00:15:20
	System	05 Aug 2020 00:15:20

US3352015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:10:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-04T20:15:15', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'bbc6bc24-a9d9-4f28-b592-cfa9af8262e0' User entered '04 Aug 2020 20:15'	System	05 Aug 2020 00:15:20
	System	05 Aug 2020 00:15:20

US3352015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:10:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '04 Aug 2020 20:11'	System	04 Aug 2020 20:45:19

US3352015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:10:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '05 Aug 2020 11:59'	System	04 Aug 2020 20:45:19

US3352015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
Data entry locked.	System	04 Aug 2020 20:45:19
User entered 'Day 2'	System	04 Aug 2020 20:45:19

US3352015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:10:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-05T18:47:56', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '1bc9d83a-809d-4763-baf7-6ab5d768cb26' User entered 'Yes (Y)'	System	05 Aug 2020 22:48:23
	System	05 Aug 2020 22:48:23

US3352015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:10:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-05T18:48:14', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '1bc9d83a-809d-4763-baf7-6ab5d768cb26' User entered '98.5'	System	05 Aug 2020 22:48:23
	System	05 Aug 2020 22:48:23

US3352015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-05T18:48:18', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '1bc9d83a-809d-4763-baf7-6ab5d768cb26' User entered 'No (N)'	System	05 Aug 2020 22:48:23
	System	05 Aug 2020 22:48:23

US3352015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:10:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-05T18:48:21', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '1bc9d83a-809d-4763-baf7-6ab5d768cb26' User entered '05 Aug 2020 18:48'	System	05 Aug 2020 22:48:23
	System	05 Aug 2020 22:48:23

US3352015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:10:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '05 Aug 2020 12:00'	System	04 Aug 2020 20:45:19

US3352015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:10:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '06 Aug 2020 11:59'	System	04 Aug 2020 20:45:19

US3352015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
Data entry locked.	System	04 Aug 2020 20:45:19
User entered 'Day 3'	System	04 Aug 2020 20:45:19

US3352015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:10:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-06T18:44:22', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '5936bdd4-1fbc-44fd-8956-4e8f86b72db1' User entered 'Yes (Y)'	System	06 Aug 2020 22:44:36
	System	06 Aug 2020 22:44:36

US3352015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:10:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-06T18:44:26', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '5936bdd4-1fbc-44fd-8956-4e8f86b72db1' User entered '99.0'	System	06 Aug 2020 22:44:36
	System	06 Aug 2020 22:44:36

US3352015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-06T18:44:29', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '5936bdd4-1fbc-44fd-8956-4e8f86b72db1' User entered 'No (N)'	System	06 Aug 2020 22:44:36
	System	06 Aug 2020 22:44:36

US3352015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:10:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-06T18:44:32', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '5936bdd4-1fbc-44fd-8956-4e8f86b72db1' User entered '06 Aug 2020 18:44'	System	06 Aug 2020 22:44:36
	System	06 Aug 2020 22:44:36

US3352015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:10:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 20:45:19

US3352015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:10:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 20:45:19

US3352015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
Data entry locked.	System	04 Aug 2020 20:45:19
User entered 'Day 4'	System	04 Aug 2020 20:45:19

US3352015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:10:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-07T19:36:03', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '5c619516-d84e-4236-b860-0ce396cef52a' User entered 'Yes (Y)'	System	07 Aug 2020 23:36:24
	System	07 Aug 2020 23:36:24

US3352015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:10:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-07T19:36:08', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '5c619516-d84e-4236-b860-0ce396cef52a' User entered '98.4'	System	07 Aug 2020 23:36:24
	System	07 Aug 2020 23:36:24

US3352015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-07T19:36:10', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '5c619516-d84e-4236-b860-0ce396cef52a' User entered 'No (N)'	System	07 Aug 2020 23:36:24
	System	07 Aug 2020 23:36:24

US3352015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:10:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-07T19:36:19', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '5c619516-d84e-4236-b860-0ce396cef52a' User entered '07 Aug 2020 19:36'	System	07 Aug 2020 23:36:24
	System	07 Aug 2020 23:36:24

US3352015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:10:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '07 Aug 2020 12:00'	System	04 Aug 2020 20:45:19

US3352015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:10:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '08 Aug 2020 11:59'	System	04 Aug 2020 20:45:19

US3352015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
Data entry locked.	System	04 Aug 2020 20:45:19
User entered 'Day 5'	System	04 Aug 2020 20:45:19

US3352015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:10:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-08T15:11:52', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'f4c5efff-8ecd-4f45-8dcb-92a36b7f92a6'	System	08 Aug 2020 19:12:03
User entered 'Yes (Y)'	System	08 Aug 2020 19:12:03

US3352015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:10:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-08T15:11:56', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'f4c5efff-8ecd-4f45-8dcb-92a36b7f92a6' User entered '98.3'	System	08 Aug 2020 19:12:03
	System	08 Aug 2020 19:12:03

US3352015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-08T15:11:59', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'f4c5efff-8ecd-4f45-8dcb-92a36b7f92a6'	System	08 Aug 2020 19:12:03
User entered 'No (N)'	System	08 Aug 2020 19:12:03

US3352015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:10:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-08T15:12:01', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'f4c5efff-8ecd-4f45-8dcb-92a36b7f92a6'	System	08 Aug 2020 19:12:03
User entered '08 Aug 2020 15:12'	System	08 Aug 2020 19:12:03

US3352015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:10:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '08 Aug 2020 12:00'	System	04 Aug 2020 20:45:19

US3352015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:10:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '09 Aug 2020 11:59'	System	04 Aug 2020 20:45:19

US3352015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
Data entry locked.	System	04 Aug 2020 20:45:19
User entered 'Day 6'	System	04 Aug 2020 20:45:19

US3352015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:10:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-09T17:49:01', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'b9f3e929-0243-4808-9fb2-eac59e149067'	System	09 Aug 2020 21:49:12
User entered 'Yes (Y)'	System	09 Aug 2020 21:49:12

US3352015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:10:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-09T17:49:05', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'b9f3e929-0243-4808-9fb2-eac59e149067' User entered '98.5'	System	09 Aug 2020 21:49:12
	System	09 Aug 2020 21:49:12

US3352015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-09T17:49:08', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'b9f3e929-0243-4808-9fb2-eac59e149067'	System	09 Aug 2020 21:49:12
User entered 'No (N)'	System	09 Aug 2020 21:49:12

US3352015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:10:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-09T17:49:10', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'b9f3e929-0243-4808-9fb2-eac59e149067' User entered '09 Aug 2020 17:49'	System	09 Aug 2020 21:49:12
	System	09 Aug 2020 21:49:12

US3352015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:10:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '09 Aug 2020 12:00'	System	04 Aug 2020 20:45:19

US3352015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:10:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '10 Aug 2020 11:59'	System	04 Aug 2020 20:45:19

US3352015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
Data entry locked.	System	04 Aug 2020 20:45:19
User entered 'Day 7'	System	04 Aug 2020 20:45:19

US3352015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:10:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-10T16:49:45', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '2be2da34-392a-41a1-b506-334eef71fcea' User entered 'Yes (Y)'	System	10 Aug 2020 20:50:02
	System	10 Aug 2020 20:50:02

US3352015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:10:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-10T16:49:54', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '2be2da34-392a-41a1-b506-334eef71fcea' User entered '98.2'	System	10 Aug 2020 20:50:02
	System	10 Aug 2020 20:50:02

US3352015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-10T16:49:58', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '2be2da34-392a-41a1-b506-334eef71fcea'	System	10 Aug 2020 20:50:02
User entered 'No (N)'	System	10 Aug 2020 20:50:02

US3352015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:10:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-10T16:50:00', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '2be2da34-392a-41a1-b506-334eef71fcea' User entered '10 Aug 2020 16:50'	System	10 Aug 2020 20:50:02
	System	10 Aug 2020 20:50:02

US3352015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:10:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '10 Aug 2020 12:00'	System	04 Aug 2020 20:45:19

US3352015

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:10:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '11 Aug 2020 11:59'	System	04 Aug 2020 20:45:19

US3352015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
Data entry locked.	System	04 Aug 2020 20:45:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Aug 2020 20:45:19

US3352015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:10:26

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 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-04T17:01:15', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'af963bbe-bcbc-406d-91ef-650fbb985172'	System	04 Aug 2020 21:02:08
User entered 'None (1)'	System	04 Aug 2020 21:02:08

US3352015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:10:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-04T17:01:24', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'af963bbe-bcbc-406d-91ef-650fbb985172'	System	04 Aug 2020 21:02:08
User entered 'No (N)'	System	04 Aug 2020 21:02:08

US3352015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-04T17:01:35', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'af963bbe-bcbc-406d-91ef-650fbb985172'	System	04 Aug 2020 21:02:08
User entered 'No (N)'	System	04 Aug 2020 21:02:08

US3352015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:10:26

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 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-04T17:01:47', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'af963bbe-bcbc-406d-91ef-650fbb985172'	System	04 Aug 2020 21:02:08
User entered 'None (1)'	System	04 Aug 2020 21:02:08

US3352015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:10:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-04T17:01:52', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'af963bbe-bcbc-406d-91ef-650fbb985172' User entered '04 Aug 2020 17:01'	System	04 Aug 2020 21:02:08
	System	04 Aug 2020 21:02:08

US3352015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:10:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '04 Aug 2020 16:46'	System	04 Aug 2020 20:45:19

US3352015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:10:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '04 Aug 2020 19:16'	System	04 Aug 2020 20:45:19

US3352015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
Data entry locked.	System	04 Aug 2020 20:45:19
User entered 'Day 1, after vaccination (at home)'	System	04 Aug 2020 20:45:19

US3352015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:10:26

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 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-04T20:15:29', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '92b199b1-4f83-4835-8562-fdfa6b8e8aac'	System	05 Aug 2020 00:15:48
User entered 'None (1)'	System	05 Aug 2020 00:15:48

US3352015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:10:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-04T20:15:32', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '92b199b1-4f83-4835-8562-fdfa6b8e8aac'	System	05 Aug 2020 00:15:48
User entered 'No (N)'	System	05 Aug 2020 00:15:48

US3352015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-04T20:15:39', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '92b199b1-4f83-4835-8562-fdfa6b8e8aac'	System	05 Aug 2020 00:15:48
User entered 'No (N)'	System	05 Aug 2020 00:15:48

US3352015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:10:26

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 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-04T20:15:43', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '92b199b1-4f83-4835-8562-fdfa6b8e8aac'	System	05 Aug 2020 00:15:48
User entered 'None (1)'	System	05 Aug 2020 00:15:48

US3352015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:10:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-04T20:15:46', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '92b199b1-4f83-4835-8562-fdfa6b8e8aac'	System	05 Aug 2020 00:15:48
User entered '04 Aug 2020 20:15'	System	05 Aug 2020 00:15:48

US3352015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:10:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '04 Aug 2020 20:11'	System	04 Aug 2020 20:45:19

US3352015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:10:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '05 Aug 2020 11:59'	System	04 Aug 2020 20:45:19

US3352015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
Data entry locked.	System	04 Aug 2020 20:45:19
User entered 'Day 2'	System	04 Aug 2020 20:45:19

US3352015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:10:26

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 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-05T12:01:42', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '53ef6c7a-b16b-4128-aa4a-024c6bca1d05'	System	05 Aug 2020 16:01:56
User entered 'Does not interfere with activity (2)'	System	05 Aug 2020 16:01:56

US3352015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:10:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-05T12:01:44', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '53ef6c7a-b16b-4128-aa4a-024c6bca1d05' User entered 'No (N)'	System	05 Aug 2020 16:01:56
	System	05 Aug 2020 16:01:56

US3352015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-05T12:01:48', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '53ef6c7a-b16b-4128-aa4a-024c6bca1d05' User entered 'No (N)'	System	05 Aug 2020 16:01:56
	System	05 Aug 2020 16:01:56

US3352015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:10:26

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 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-05T12:01:50', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '53ef6c7a-b16b-4128-aa4a-024c6bca1d05'	System	05 Aug 2020 16:01:56
User entered 'None (1)'	System	05 Aug 2020 16:01:56

US3352015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:10:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-05T12:01:53', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '53ef6c7a-b16b-4128-aa4a-024c6bca1d05' User entered '05 Aug 2020 12:01'	System	05 Aug 2020 16:01:56
	System	05 Aug 2020 16:01:56

US3352015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:10:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '05 Aug 2020 12:00'	System	04 Aug 2020 20:45:19

US3352015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:10:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '06 Aug 2020 11:59'	System	04 Aug 2020 20:45:19

US3352015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
Data entry locked.	System	04 Aug 2020 20:45:19
User entered 'Day 3'	System	04 Aug 2020 20:45:19

US3352015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:10:26

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 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-06T18:44:36', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '368a4027-001f-4723-8937-cff0639319e7'	System	06 Aug 2020 22:45:19
User entered 'Does not interfere with activity (2)'	System	06 Aug 2020 22:45:19

US3352015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:10:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-06T18:44:38', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '368a4027-001f-4723-8937-cff0639319e7' User entered 'No (N)'	System	06 Aug 2020 22:45:19
	System	06 Aug 2020 22:45:19

US3352015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-06T18:44:40', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '368a4027-001f-4723-8937-cff0639319e7' User entered 'Yes (Y)'	System	06 Aug 2020 22:45:19
	System	06 Aug 2020 22:45:19

US3352015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:10:26

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 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-06T18:44:53', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '368a4027-001f-4723-8937-cff0639319e7' User entered '30'	System	06 Aug 2020 22:45:19
	System	06 Aug 2020 22:45:19

US3352015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:10:26

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 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-06T18:44:56', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '368a4027-001f-4723-8937-cff0639319e7'	System	06 Aug 2020 22:45:19
User entered 'None (1)'	System	06 Aug 2020 22:45:19

US3352015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:10:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-06T18:44:59', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '368a4027-001f-4723-8937-cff0639319e7' User entered '06 Aug 2020 18:44'	System	06 Aug 2020 22:45:19
	System	06 Aug 2020 22:45:19

US3352015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:10:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 20:45:19

US3352015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:10:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 20:45:19

US3352015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
Data entry locked.	System	04 Aug 2020 20:45:19
User entered 'Day 4'	System	04 Aug 2020 20:45:19

US3352015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:10:26

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 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-07T19:36:23', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'd18899c0-ca0a-4c9f-8f11-2b31e589a616' User entered 'None (1)'	System	07 Aug 2020 23:36:35
	System	07 Aug 2020 23:36:35

US3352015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:10:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-07T19:36:25', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'd18899c0-ca0a-4c9f-8f11-2b31e589a616'	System	07 Aug 2020 23:36:35
User entered 'No (N)'	System	07 Aug 2020 23:36:35

US3352015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-07T19:36:27', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'd18899c0-ca0a-4c9f-8f11-2b31e589a616' User entered 'No (N)'	System	07 Aug 2020 23:36:35
	System	07 Aug 2020 23:36:35

US3352015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:10:26

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 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-07T19:36:30', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'd18899c0-ca0a-4c9f-8f11-2b31e589a616' User entered 'None (1)'	System	07 Aug 2020 23:36:35
	System	07 Aug 2020 23:36:35

US3352015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:10:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-07T19:36:32', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'd18899c0-ca0a-4c9f-8f11-2b31e589a616'	System	07 Aug 2020 23:36:35
User entered '07 Aug 2020 19:36'	System	07 Aug 2020 23:36:35

US3352015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:10:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '07 Aug 2020 12:00'	System	04 Aug 2020 20:45:19

US3352015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:10:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '08 Aug 2020 11:59'	System	04 Aug 2020 20:45:19

US3352015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
Data entry locked.	System	04 Aug 2020 20:45:19
User entered 'Day 5'	System	04 Aug 2020 20:45:19

US3352015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:10:26

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 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-08T15:12:05', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '469e4572-a426-48cc-bfe1-85141e9f7938'	System	08 Aug 2020 19:12:15
User entered 'None (1)'	System	08 Aug 2020 19:12:15

US3352015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:10:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-08T15:12:07', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '469e4572-a426-48cc-bfe1-85141e9f7938'	System	08 Aug 2020 19:12:15
User entered 'No (N)'	System	08 Aug 2020 19:12:15

US3352015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-08T15:12:09', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '469e4572-a426-48cc-bfe1-85141e9f7938'	System	08 Aug 2020 19:12:15
User entered 'No (N)'	System	08 Aug 2020 19:12:15

US3352015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:10:26

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 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-08T15:12:11', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '469e4572-a426-48cc-bfe1-85141e9f7938'	System	08 Aug 2020 19:12:15
User entered 'None (1)'	System	08 Aug 2020 19:12:15

US3352015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:10:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-08T15:12:14', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '469e4572-a426-48cc-bfe1-85141e9f7938' User entered '08 Aug 2020 15:12'	System	08 Aug 2020 19:12:15
	System	08 Aug 2020 19:12:15

US3352015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:10:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '08 Aug 2020 12:00'	System	04 Aug 2020 20:45:19

US3352015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:10:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '09 Aug 2020 11:59'	System	04 Aug 2020 20:45:19

US3352015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
Data entry locked.	System	04 Aug 2020 20:45:19
User entered 'Day 6'	System	04 Aug 2020 20:45:19

US3352015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:10:26

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 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-09T17:49:13', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '872f3126-0ba1-4199-9e1a-403496e05923' User entered 'None (1)'	System	09 Aug 2020 21:49:38
	System	09 Aug 2020 21:49:38

US3352015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:10:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-09T17:49:15', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '872f3126-0ba1-4199-9e1a-403496e05923' User entered 'No (N)'	System	09 Aug 2020 21:49:38
	System	09 Aug 2020 21:49:38

US3352015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-09T17:49:17', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '872f3126-0ba1-4199-9e1a-403496e05923' User entered 'No (N)'	System	09 Aug 2020 21:49:38
	System	09 Aug 2020 21:49:38

US3352015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:10:26

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 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-09T17:49:32', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '872f3126-0ba1-4199-9e1a-403496e05923' User entered 'None (1)'	System	09 Aug 2020 21:49:38
	System	09 Aug 2020 21:49:38

US3352015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:10:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-09T17:49:34', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '872f3126-0ba1-4199-9e1a-403496e05923' User entered '09 Aug 2020 17:49'	System	09 Aug 2020 21:49:38
	System	09 Aug 2020 21:49:38

US3352015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:10:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '09 Aug 2020 12:00'	System	04 Aug 2020 20:45:19

US3352015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:10:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '10 Aug 2020 11:59'	System	04 Aug 2020 20:45:19

US3352015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
Data entry locked.	System	04 Aug 2020 20:45:19
User entered 'Day 7'	System	04 Aug 2020 20:45:19

US3352015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:10:26

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 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-10T16:50:03', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'e7f2c389-a11b-4130-b36d-03428845dda8' User entered 'None (1)'	System	10 Aug 2020 20:50:14
	System	10 Aug 2020 20:50:14

US3352015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:10:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-10T16:50:05', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'e7f2c389-a11b-4130-b36d-03428845dda8' User entered 'No (N)'	System	10 Aug 2020 20:50:14
	System	10 Aug 2020 20:50:14

US3352015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-10T16:50:06', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'e7f2c389-a11b-4130-b36d-03428845dda8' User entered 'No (N)'	System	10 Aug 2020 20:50:14
	System	10 Aug 2020 20:50:14

US3352015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:10:26

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 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-10T16:50:08', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'e7f2c389-a11b-4130-b36d-03428845dda8' User entered 'None (1)'	System	10 Aug 2020 20:50:14
	System	10 Aug 2020 20:50:14

US3352015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:10:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-10T16:50:10', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'e7f2c389-a11b-4130-b36d-03428845dda8' User entered '10 Aug 2020 16:50'	System	10 Aug 2020 20:50:14
	System	10 Aug 2020 20:50:14

US3352015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:10:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '10 Aug 2020 12:00'	System	04 Aug 2020 20:45:19

US3352015

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:10:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '11 Aug 2020 11:59'	System	04 Aug 2020 20:45:19

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
Data entry locked.	System	04 Aug 2020 20:45:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Aug 2020 20:45:19

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-04T17:01:59', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '25dedcaa-0ef2-4eef-be6c-d99715312ddd' User entered 'None (0)'	System	04 Aug 2020 21:02:17
	System	04 Aug 2020 21:02:17

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-04T17:02:01', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '25dedcaa-0ef2-4eef-be6c-d99715312ddd' User entered 'None (0)'	System	04 Aug 2020 21:02:17
	System	04 Aug 2020 21:02:17

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-04T17:02:03', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '25dedcaa-0ef2-4eef-be6c-d99715312ddd' User entered 'None (0)'	System	04 Aug 2020 21:02:17
	System	04 Aug 2020 21:02:17

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-04T17:02:05', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '25dedcaa-0ef2-4eef-be6c-d99715312ddd' User entered 'None (0)'	System	04 Aug 2020 21:02:17
	System	04 Aug 2020 21:02:17

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-04T17:02:07', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '25dedcaa-0ef2-4eef-be6c-d99715312ddd' User entered 'None (0)'	System	04 Aug 2020 21:02:17
	System	04 Aug 2020 21:02:17

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-04T17:02:09', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '25dedcaa-0ef2-4eef-be6c-d99715312ddd' User entered 'None (0)'	System	04 Aug 2020 21:02:17
	System	04 Aug 2020 21:02:17

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:26

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 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-04T17:02:12', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '25dedcaa-0ef2-4eef-be6c-d99715312ddd' User entered 'No (N)'	System	04 Aug 2020 21:02:17
	System	04 Aug 2020 21:02:17

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-04T17:02:15', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '25dedcaa-0ef2-4eef-be6c-d99715312ddd' User entered '04 Aug 2020 17:02'	System	04 Aug 2020 21:02:17
	System	04 Aug 2020 21:02:17

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '04 Aug 2020 16:46'	System	04 Aug 2020 20:45:19

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '04 Aug 2020 19:16'	System	04 Aug 2020 20:45:19

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
Data entry locked.	System	04 Aug 2020 20:45:19
User entered 'Day 1, after vaccination (at home)'	System	04 Aug 2020 20:45:19

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-04T20:15:50', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'f6fa9901-75c9-4b68-8c8f-1cdc71565bcf' User entered 'None (0)'	System	05 Aug 2020 00:16:20
	System	05 Aug 2020 00:16:20

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-04T20:15:55', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'f6fa9901-75c9-4b68-8c8f-1cdc71565bcf' User entered 'None (0)'	System	05 Aug 2020 00:16:20
	System	05 Aug 2020 00:16:20

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-04T20:15:58', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'f6fa9901-75c9-4b68-8c8f-1cdc71565bcf' User entered 'None (0)'	System	05 Aug 2020 00:16:20
	System	05 Aug 2020 00:16:20

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-04T20:16:02', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'f6fa9901-75c9-4b68-8c8f-1cdc71565bcf' User entered 'None (0)'	System	05 Aug 2020 00:16:20
	System	05 Aug 2020 00:16:20

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-04T20:16:04', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'f6fa9901-75c9-4b68-8c8f-1cdc71565bcf' User entered 'None (0)'	System	05 Aug 2020 00:16:20
	System	05 Aug 2020 00:16:20

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-04T20:16:07', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'f6fa9901-75c9-4b68-8c8f-1cdc71565bcf' User entered 'None (0)'	System	05 Aug 2020 00:16:20
	System	05 Aug 2020 00:16:20

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:26

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 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-04T20:16:15', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'f6fa9901-75c9-4b68-8c8f-1cdc71565bcf' User entered 'No (N)'	System	05 Aug 2020 00:16:20
	System	05 Aug 2020 00:16:20

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-04T20:16:18', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'f6fa9901-75c9-4b68-8c8f-1cdc71565bcf' User entered '04 Aug 2020 20:16'	System	05 Aug 2020 00:16:20
	System	05 Aug 2020 00:16:20

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '04 Aug 2020 20:11'	System	04 Aug 2020 20:45:19

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '05 Aug 2020 11:59'	System	04 Aug 2020 20:45:19

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
Data entry locked.	System	04 Aug 2020 20:45:19
User entered 'Day 2'	System	04 Aug 2020 20:45:19

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-05T12:00:40', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'ef312d66-533d-4e75-99fb-f1e715fcd78e' User entered 'None (0)'	System	05 Aug 2020 16:01:38
	System	05 Aug 2020 16:01:38

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-05T12:00:44', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'ef312d66-533d-4e75-99fb-f1e715fcd78e' User entered 'No interference with activity (1)'	System	05 Aug 2020 16:01:38
	System	05 Aug 2020 16:01:38

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-05T12:00:46', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'ef312d66-533d-4e75-99fb-f1e715fcd78e' User entered 'None (0)'	System	05 Aug 2020 16:01:38
	System	05 Aug 2020 16:01:38

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-05T12:01:16', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'ef312d66-533d-4e75-99fb-f1e715fcd78e' User entered 'None (0)'	System	05 Aug 2020 16:01:38
	System	05 Aug 2020 16:01:38

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-05T12:01:18', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'ef312d66-533d-4e75-99fb-f1e715fcd78e' User entered 'None (0)'	System	05 Aug 2020 16:01:38
	System	05 Aug 2020 16:01:38

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-05T12:01:20', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'ef312d66-533d-4e75-99fb-f1e715fcd78e' User entered 'None (0)'	System	05 Aug 2020 16:01:38
	System	05 Aug 2020 16:01:38

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:26

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 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-05T12:01:23', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'ef312d66-533d-4e75-99fb-f1e715fcd78e' User entered 'No (N)'	System	05 Aug 2020 16:01:38
	System	05 Aug 2020 16:01:38

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-05T12:01:35', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'ef312d66-533d-4e75-99fb-f1e715fcd78e' User entered '05 Aug 2020 12:01'	System	05 Aug 2020 16:01:38
	System	05 Aug 2020 16:01:38

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '05 Aug 2020 12:00'	System	04 Aug 2020 20:45:19

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '06 Aug 2020 11:59'	System	04 Aug 2020 20:45:19

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
Data entry locked.	System	04 Aug 2020 20:45:19
User entered 'Day 3'	System	04 Aug 2020 20:45:19

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-06T18:45:03', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '68a8950c-84c7-4d62-93f4-7d46fa230e3c' User entered 'None (0)'	System	06 Aug 2020 22:45:25
	System	06 Aug 2020 22:45:25

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-06T18:45:05', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '68a8950c-84c7-4d62-93f4-7d46fa230e3c'	System	06 Aug 2020 22:45:25
User entered 'No interference with activity (1)'	System	06 Aug 2020 22:45:25

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-06T18:45:10', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '68a8950c-84c7-4d62-93f4-7d46fa230e3c' User entered 'None (0)'	System	06 Aug 2020 22:45:25
	System	06 Aug 2020 22:45:25

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-06T18:45:12', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '68a8950c-84c7-4d62-93f4-7d46fa230e3c' User entered 'None (0)'	System	06 Aug 2020 22:45:25
	System	06 Aug 2020 22:45:25

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-06T18:45:13', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '68a8950c-84c7-4d62-93f4-7d46fa230e3c' User entered 'None (0)'	System	06 Aug 2020 22:45:25
	System	06 Aug 2020 22:45:25

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-06T18:45:15', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '68a8950c-84c7-4d62-93f4-7d46fa230e3c' User entered 'None (0)'	System	06 Aug 2020 22:45:25
	System	06 Aug 2020 22:45:25

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:26

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 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-06T18:45:17', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '68a8950c-84c7-4d62-93f4-7d46fa230e3c' User entered 'No (N)'	System	06 Aug 2020 22:45:25
	System	06 Aug 2020 22:45:25

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-06T18:45:20', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '68a8950c-84c7-4d62-93f4-7d46fa230e3c' User entered '06 Aug 2020 18:45'	System	06 Aug 2020 22:45:25
	System	06 Aug 2020 22:45:25

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 20:45:19

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 20:45:19

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
Data entry locked.	System	04 Aug 2020 20:45:19
User entered 'Day 4'	System	04 Aug 2020 20:45:19

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-07T19:36:35', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '32bcdcb8-b543-4e5f-8303-b2e305ee7b7b' User entered 'None (0)'	System	07 Aug 2020 23:36:52
	System	07 Aug 2020 23:36:52

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-07T19:36:37', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '32bcdcb8-b543-4e5f-8303-b2e305ee7b7b' User entered 'None (0)'	System	07 Aug 2020 23:36:52
	System	07 Aug 2020 23:36:52

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-07T19:36:39', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '32bcdcb8-b543-4e5f-8303-b2e305eefb7b' User entered 'None (0)'	System	07 Aug 2020 23:36:52
	System	07 Aug 2020 23:36:52

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-07T19:36:41', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '32bcdcb8-b543-4e5f-8303-b2e305ee7b7b' User entered 'None (0)'	System	07 Aug 2020 23:36:52
	System	07 Aug 2020 23:36:52

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-07T19:36:42', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '32bcdcb8-b543-4e5f-8303-b2e305ee7b7b' User entered 'None (0)'	System	07 Aug 2020 23:36:52
	System	07 Aug 2020 23:36:52

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-07T19:36:44', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '32bcdcb8-b543-4e5f-8303-b2e305ee7b7b' User entered 'None (0)'	System	07 Aug 2020 23:36:52
	System	07 Aug 2020 23:36:52

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:26

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 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-07T19:36:47', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '32bcdcb8-b543-4e5f-8303-b2e305ee7b7b' User entered 'No (N)'	System	07 Aug 2020 23:36:52
	System	07 Aug 2020 23:36:52

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-07T19:36:50', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '32bcdcb8-b543-4e5f-8303-b2e305ee7b7b' User entered '07 Aug 2020 19:36'	System	07 Aug 2020 23:36:52
	System	07 Aug 2020 23:36:52

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '07 Aug 2020 12:00'	System	04 Aug 2020 20:45:19

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '08 Aug 2020 11:59'	System	04 Aug 2020 20:45:19

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
Data entry locked.	System	04 Aug 2020 20:45:19
User entered 'Day 5'	System	04 Aug 2020 20:45:19

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-08T15:12:17', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '751260dc-006c-467a-b9ff-97f4fc0dc256' User entered 'None (0)'	System	08 Aug 2020 19:12:30
	System	08 Aug 2020 19:12:30

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-08T15:12:18', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '751260dc-006c-467a-b9ff-97f4fc0dc256' User entered 'None (0)'	System	08 Aug 2020 19:12:30
	System	08 Aug 2020 19:12:30

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-08T15:12:20', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '751260dc-006c-467a-b9ff-97f4fc0dc256' User entered 'None (0)'	System	08 Aug 2020 19:12:30
	System	08 Aug 2020 19:12:30

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-08T15:12:21', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '751260dc-006c-467a-b9ff-97f4fc0dc256' User entered 'None (0)'	System	08 Aug 2020 19:12:30
	System	08 Aug 2020 19:12:30

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-08T15:12:23', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '751260dc-006c-467a-b9ff-97f4fc0dc256' User entered 'None (0)'	System	08 Aug 2020 19:12:30
	System	08 Aug 2020 19:12:30

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-08T15:12:24', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '751260dc-006c-467a-b9ff-97f4fc0dc256' User entered 'None (0)'	System	08 Aug 2020 19:12:30
	System	08 Aug 2020 19:12:30

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:26

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 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-08T15:12:26', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '751260dc-006c-467a-b9ff-97f4fc0dc256' User entered 'No (N)'	System	08 Aug 2020 19:12:30
	System	08 Aug 2020 19:12:30

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-08T15:12:28', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '751260dc-006c-467a-b9ff-97f4fc0dc256' User entered '08 Aug 2020 15:12'	System	08 Aug 2020 19:12:30
	System	08 Aug 2020 19:12:30

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '08 Aug 2020 12:00'	System	04 Aug 2020 20:45:19

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '09 Aug 2020 11:59'	System	04 Aug 2020 20:45:19

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
Data entry locked.	System	04 Aug 2020 20:45:19
User entered 'Day 6'	System	04 Aug 2020 20:45:19

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-09T17:49:38', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'b82b561e-ea64-413a-a093-d2aa1706325c' User entered 'None (0)'	System	09 Aug 2020 21:49:54
	System	09 Aug 2020 21:49:54

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-09T17:49:40', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'b82b561e-ea64-413a-a093-d2aa1706325c' User entered 'None (0)'	System	09 Aug 2020 21:49:54
	System	09 Aug 2020 21:49:54

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-09T17:49:43', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'b82b561e-ea64-413a-a093-d2aa1706325c' User entered 'None (0)'	System	09 Aug 2020 21:49:54
	System	09 Aug 2020 21:49:54

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-09T17:49:44', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'b82b561e-ea64-413a-a093-d2aa1706325c' User entered 'None (0)'	System	09 Aug 2020 21:49:54
	System	09 Aug 2020 21:49:54

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-09T17:49:45', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'b82b561e-ea64-413a-a093-d2aa1706325c' User entered 'None (0)'	System	09 Aug 2020 21:49:54
	System	09 Aug 2020 21:49:54

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-09T17:49:47', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'b82b561e-ea64-413a-a093-d2aa1706325c' User entered 'None (0)'	System	09 Aug 2020 21:49:54
	System	09 Aug 2020 21:49:54

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:26

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 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-09T17:49:49', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'b82b561e-ea64-413a-a093-d2aa1706325c' User entered 'No (N)'	System	09 Aug 2020 21:49:54
	System	09 Aug 2020 21:49:54

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-09T17:49:50', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'b82b561e-ea64-413a-a093-d2aa1706325c' User entered '09 Aug 2020 17:49'	System	09 Aug 2020 21:49:54
	System	09 Aug 2020 21:49:54

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '09 Aug 2020 12:00'	System	04 Aug 2020 20:45:19

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '10 Aug 2020 11:59'	System	04 Aug 2020 20:45:19

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
Data entry locked.	System	04 Aug 2020 20:45:19
User entered 'Day 7'	System	04 Aug 2020 20:45:19

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-10T16:50:13', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '47d3d431-8977-4b8c-8b93-fd581590ccc2' User entered 'None (0)'	System	10 Aug 2020 20:50:26
	System	10 Aug 2020 20:50:26

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-10T16:50:14', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '47d3d431-8977-4b8c-8b93-fd581590ccc2' User entered 'None (0)'	System	10 Aug 2020 20:50:26
	System	10 Aug 2020 20:50:26

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-10T16:50:15', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '47d3d431-8977-4b8c-8b93-fd581590ccc2' User entered 'None (0)'	System	10 Aug 2020 20:50:26
	System	10 Aug 2020 20:50:26

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-10T16:50:16', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '47d3d431-8977-4b8c-8b93-fd581590ccc2' User entered 'None (0)'	System	10 Aug 2020 20:50:26
	System	10 Aug 2020 20:50:26

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-10T16:50:18', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '47d3d431-8977-4b8c-8b93-fd581590ccc2' User entered 'None (0)'	System	10 Aug 2020 20:50:26
	System	10 Aug 2020 20:50:26

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-10T16:50:19', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '47d3d431-8977-4b8c-8b93-fd581590ccc2' User entered 'None (0)'	System	10 Aug 2020 20:50:26
	System	10 Aug 2020 20:50:26

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:26

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 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-10T16:50:21', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '47d3d431-8977-4b8c-8b93-fd581590ccc2' User entered 'No (N)'	System	10 Aug 2020 20:50:26
	System	10 Aug 2020 20:50:26

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-08-10T16:50:23', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '47d3d431-8977-4b8c-8b93-fd581590ccc2' User entered '10 Aug 2020 16:50'	System	10 Aug 2020 20:50:26
	System	10 Aug 2020 20:50:26

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '10 Aug 2020 12:00'	System	04 Aug 2020 20:45:19

US3352015

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '11 Aug 2020 11:59'	System	04 Aug 2020 20:45:19

US3352015

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:00
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 20:23:47

US3352015

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:00
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '11 Aug 2020'	(b) (4), (b) (6)	11 Aug 2020 20:23:47

US3352015

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:00
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	11 Aug 2020 20:23:47

US3352015

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:00
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 20:23:47

US3352015

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:00
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 20:23:40

US3352015

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:05:00
User entered 'I'	System	11 Aug 2020 20:23:40

US3352015

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:39:09
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4)	19 Aug 2020 16:06:07

US3352015

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:39:09
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '19 Aug 2020'	Yulexis Amestoy (b) (4)	19 Aug 2020 16:06:07

US3352015

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:39:09
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Contact Made (CONTACT MADE)'	Yulexis Amestoy (b) (4)	19 Aug 2020 16:06:07

US3352015

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:39:09
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered empty.	Yulexis Amestoy (b) (4)	19 Aug 2020 16:06:07

US3352015

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:39:15
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4)	19 Aug 2020 16:06:13

US3352015

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:39:15
User entered 'I'	System	19 Aug 2020 16:06:13

US3352015

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:46:25
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4)	26 Aug 2020 14:25:53

US3352015

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:46:25
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '26 Aug 2020'	Yulexis Amestoy (b) (4)	26 Aug 2020 14:25:53

US3352015

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:46:25
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Contact Made (CONTACT MADE)'	Yulexis Amestoy (b) (4)	26 Aug 2020 14:25:53

US3352015

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:46:25
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered empty.	Yulexis Amestoy (b) (4)	26 Aug 2020 14:25:53

US3352015

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:46:25
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4)	26 Aug 2020 14:25:59

US3352015

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:46:25
User entered 'I'	System	26 Aug 2020 14:25:59

US3352015

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:10:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:42
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 20:43:36

US3352015

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:10:26

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:42
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '3 Sep 2020'	(b) (4), (b) (6)	03 Sep 2020 20:43:36

US3352015

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:42
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	03 Sep 2020 20:43:36

US3352015

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:10:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:42
User entered 'VISIT2'	System	03 Sep 2020 20:43:36

US3352015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:26

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:42
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	03 Sep 2020 20:44:59

US3352015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:26

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:42
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 20:44:59

US3352015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:42
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '3 Sep 2020'	(b) (4), (b) (6)	03 Sep 2020 20:44:59

US3352015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:42
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '14:05'	(b) (4), (b) (6)	03 Sep 2020 20:44:59

US3352015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:42
User entered '3 Sep 2020 14:05'	System	03 Sep 2020 20:44:59

US3352015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:42
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '36.9' C	(b) (4), (b) (6)	03 Sep 2020 20:44:59

US3352015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:42
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Oral (Oral)'	(b) (4), (b) (6)	03 Sep 2020 20:44:59

US3352015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:42
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 20:44:59

US3352015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:42
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '97'	(b) (4), (b) (6)	03 Sep 2020 20:44:59

US3352015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:42
User entered 'bpm'	System	03 Sep 2020 20:44:59

US3352015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:42
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '15'	(b) (4), (b) (6)	03 Sep 2020 20:44:59

US3352015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:42
User entered 'breaths/min'	System	03 Sep 2020 20:44:59

US3352015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:42
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '111'	(b) (4), (b) (6)	03 Sep 2020 20:44:59

US3352015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:42
User entered 'mmHg'	System	03 Sep 2020 20:44:59

US3352015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:42
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '75'	(b) (4), (b) (6)	03 Sep 2020 20:44:59

US3352015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:10:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:42
User entered 'mmHg'	System	03 Sep 2020 20:44:59

US3352015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:26

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:42
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	03 Sep 2020 20:44:59

US3352015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:26

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:42
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 20:44:59

US3352015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:42
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '3 Sep 2020'	(b) (4), (b) (6)	03 Sep 2020 20:44:59

US3352015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:42
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '15:40'	(b) (4), (b) (6)	03 Sep 2020 20:44:59

US3352015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:42
User entered '3 Sep 2020 15:40'	System	03 Sep 2020 20:44:59

US3352015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:42
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '36.4' C	(b) (4), (b) (6)	03 Sep 2020 20:44:59

US3352015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:42
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Oral (Oral)'	(b) (4), (b) (6)	03 Sep 2020 20:44:59

US3352015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:42
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 20:44:59

US3352015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:42
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '73'	(b) (4), (b) (6)	03 Sep 2020 20:44:59

US3352015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:42
User entered 'bpm'	System	03 Sep 2020 20:44:59

US3352015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:42
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '13'	(b) (4), (b) (6)	03 Sep 2020 20:44:59

US3352015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:42
User entered 'breaths/min'	System	03 Sep 2020 20:44:59

US3352015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:42
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '117'	(b) (4), (b) (6)	03 Sep 2020 20:44:59

US3352015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:42
User entered 'mmHg'	System	03 Sep 2020 20:44:59

US3352015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:42
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '72'	(b) (4), (b) (6)	03 Sep 2020 20:44:59

US3352015

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:10:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:42
User entered 'mmHg'	System	03 Sep 2020 20:44:59

US3352015

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:10:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:42
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 20:46:04

US3352015

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:10:26

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:42
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 20:46:04

US3352015

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:10:26

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:42
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 19:17:46

US3352015

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:10:26

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:42
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 19:17:46

US3352015

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:10:26

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)	30 Apr 2021 09:21:42
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 19:17:46

US3352015

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:10:26

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:42
User entered 'MRNA-1273 OR PLACEBO'	System	03 Sep 2020 19:17:46

US3352015

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:10:26

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:42
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '3 Sep 2020'	(b) (4), (b) (6)	03 Sep 2020 19:17:46

US3352015

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:42
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '15:10'	(b) (4), (b) (6)	03 Sep 2020 19:17:46

US3352015

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:42
User entered '3 Sep 2020 15:10'	System	03 Sep 2020 19:17:46

US3352015

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:42
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	03 Sep 2020 19:17:46

US3352015

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:42
User entered 'ONCE'	System	03 Sep 2020 19:17:46

US3352015

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:10:26

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:42
User entered 'INTRAMUSCULAR'	System	03 Sep 2020 19:17:46

US3352015

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:42
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 20:45:17

US3352015

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:26

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:42
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '3 Sep 2020'	(b) (4), (b) (6)	03 Sep 2020 20:45:17

US3352015

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:26

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:42
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '14:49'	(b) (4), (b) (6)	03 Sep 2020 20:45:17

US3352015

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:42
User entered '3 Sep 2020 14:49'	System	03 Sep 2020 20:45:17

US3352015

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:10:26

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:42
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '3 Sep 2020'	(b) (4), (b) (6)	03 Sep 2020 20:45:42

US3352015

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:10:26

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:42
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	03 Sep 2020 20:45:42

US3352015

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:10:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:42
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 20:45:42

US3352015

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:10:26

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:42
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '14:23'	(b) (4), (b) (6)	03 Sep 2020 20:45:42

US3352015

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:42
User entered '3 Sep 2020 14:23'	System	03 Sep 2020 20:45:42

US3352015

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:10:26

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:42
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	03 Sep 2020 20:45:42

US3352015

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:10:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:42
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 20:45:42

US3352015

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:10:26

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:42
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 20:45:42

US3352015

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:10:26

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:42
User entered empty.	System	03 Sep 2020 20:45:42

US3352015

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:42
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 20:45:48

US3352015

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:21:42
User entered '1'	System	03 Sep 2020 20:45:48

US3352015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
Data entry locked.	System	03 Sep 2020 19:17:46
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 19:17:46

US3352015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:10:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-03T15:41:16', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '4725ce37-71a4-4209-b04c-f1aa99aa0782' User entered 'Yes (Y)'	System	03 Sep 2020 19:43:55
	System	03 Sep 2020 19:43:55

US3352015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:10:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-03T15:43:44', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '4725ce37-71a4-4209-b04c-f1aa99aa0782' User entered '97.5'	System	03 Sep 2020 19:43:55
	System	03 Sep 2020 19:43:55

US3352015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-03T15:43:46', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '4725ce37-71a4-4209-b04c-f1aa99aa0782' User entered 'No (N)'	System	03 Sep 2020 19:43:55
	System	03 Sep 2020 19:43:55

US3352015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:10:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-03T15:43:50', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '4725ce37-71a4-4209-b04c-f1aa99aa0782' User entered '03 Sep 2020 15:43'	System	03 Sep 2020 19:43:55
	System	03 Sep 2020 19:43:55

US3352015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:10:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '03 Sep 2020 15:30'	System	03 Sep 2020 19:17:46

US3352015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:10:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '03 Sep 2020 18:00'	System	03 Sep 2020 19:17:46

US3352015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
Data entry locked.	System	03 Sep 2020 19:17:46
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 19:17:46

US3352015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:10:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-03T19:37:53', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '8f388804-655c-4b7d-b416-a58339de2e2e' User entered 'Yes (Y)'	System	03 Sep 2020 23:38:08
	System	03 Sep 2020 23:38:08

US3352015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:10:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-03T19:37:58', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '8f388804-655c-4b7d-b416-a58339de2e2e' User entered '97.8'	System	03 Sep 2020 23:38:08
	System	03 Sep 2020 23:38:08

US3352015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-03T19:38:00', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '8f388804-655c-4b7d-b416-a58339de2e2e' User entered 'No (N)'	System	03 Sep 2020 23:38:08
	System	03 Sep 2020 23:38:08

US3352015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:10:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-03T19:38:04', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '8f388804-655c-4b7d-b416-a58339de2e2e' User entered '03 Sep 2020 19:38'	System	03 Sep 2020 23:38:08
	System	03 Sep 2020 23:38:08

US3352015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:10:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '03 Sep 2020 18:55'	System	03 Sep 2020 19:17:46

US3352015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:10:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 19:17:46

US3352015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
Data entry locked.	System	03 Sep 2020 19:17:46
User entered 'Day 2'	System	03 Sep 2020 19:17:46

US3352015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:10:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-04T12:21:35', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'd53aabe9-1fd3-46e4-a777-8f6c24f13ac5' User entered 'Yes (Y)'	System	04 Sep 2020 16:22:18
	System	04 Sep 2020 16:22:18

US3352015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:10:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-04T12:21:40', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'd53aabe9-1fd3-46e4-a777-8f6c24f13ac5' User entered '97.7'	System	04 Sep 2020 16:22:18
	System	04 Sep 2020 16:22:18

US3352015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-04T12:21:45', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'd53aabe9-1fd3-46e4-a777-8f6c24f13ac5' User entered 'Yes (Y)'	System	04 Sep 2020 16:22:18
	System	04 Sep 2020 16:22:18

US3352015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
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 'SUBJECT WAS CONTACTED AND DATA COLLECTED. SUBJECT REPORTED TAKING TYLENOL. DATA ENTERED.' (Site from System).	(b) (4), (b) (6)	14 Oct 2020 07:33:46
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).	Rosaidaliz Carreira (b) (4)	13 Oct 2020 17:41:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-04T12:21:55', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'd53aabe9-1fd3-46e4-a777-8f6c24f13ac5'	System	04 Sep 2020 16:22:18
User entered '1'	System	04 Sep 2020 16:22:18

US3352015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:10:26

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-04T12:21:55', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'd53aabe9-1fd3-46e4-a777-8f6c24f13ac5' User entered '0'	System	04 Sep 2020 16:22:18
	System	04 Sep 2020 16:22:18

US3352015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:10:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-04T12:22:15', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'd53aabe9-1fd3-46e4-a777-8f6c24f13ac5' User entered '04 Sep 2020 12:22'	System	04 Sep 2020 16:22:18
	System	04 Sep 2020 16:22:18

US3352015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:10:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 19:17:46

US3352015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:10:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 19:17:46

US3352015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
Data entry locked.	System	03 Sep 2020 19:17:46
User entered 'Day 3'	System	03 Sep 2020 19:17:46

US3352015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:10:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-05T12:23:39', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'c1e1b4ce-ed5f-4065-b739-a3bec60bf637' User entered 'Yes (Y)'	System	05 Sep 2020 16:23:49
	System	05 Sep 2020 16:23:49

US3352015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:10:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-05T12:23:43', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'c1e1b4ce-ed5f-4065-b739-a3bec60bf637' User entered '98.3'	System	05 Sep 2020 16:23:49
	System	05 Sep 2020 16:23:49

US3352015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-05T12:23:45', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'c1e1b4ce-ed5f-4065-b739-a3bec60bf637'	System	05 Sep 2020 16:23:49
User entered 'No (N)'	System	05 Sep 2020 16:23:49

US3352015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:10:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-05T12:23:48', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'c1e1b4ce-ed5f-4065-b739-a3bec60bf637' User entered '05 Sep 2020 12:23'	System	05 Sep 2020 16:23:49
	System	05 Sep 2020 16:23:49

US3352015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:10:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 19:17:46

US3352015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:10:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 19:17:46

US3352015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
Data entry locked.	System	03 Sep 2020 19:17:46
User entered 'Day 4'	System	03 Sep 2020 19:17:46

US3352015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:10:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-06T13:43:52', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '5c13e21d-afcc-4aae-8972-1797f0fbf496' User entered 'Yes (Y)'	System	06 Sep 2020 17:44:05
	System	06 Sep 2020 17:44:05

US3352015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:10:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-06T13:43:57', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '5c13e21d-afcc-4aae-8972-1797f0fbf496' User entered '98.7'	System	06 Sep 2020 17:44:05
	System	06 Sep 2020 17:44:05

US3352015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-06T13:44:00', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '5c13e21d-afcc-4aae-8972-1797f0fbf496'	System	06 Sep 2020 17:44:05
User entered 'No (N)'	System	06 Sep 2020 17:44:05

US3352015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:10:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-06T13:44:02', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '5c13e21d-afcc-4aae-8972-1797f0fbf496' User entered '06 Sep 2020 13:44'	System	06 Sep 2020 17:44:05
	System	06 Sep 2020 17:44:05

US3352015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:10:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 19:17:46

US3352015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:10:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 19:17:46

US3352015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
Data entry locked.	System	03 Sep 2020 19:17:46
User entered 'Day 5'	System	03 Sep 2020 19:17:46

US3352015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:10:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-08T07:03:34', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'a114b919-f8f8-490e-98f0-f9dc61e838a9' User entered 'Yes (Y)'	System	08 Sep 2020 11:03:49
	System	08 Sep 2020 11:03:49

US3352015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:10:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-08T07:03:37', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'a114b919-f8f8-490e-98f0-f9dc61e838a9' User entered '98.1'	System	08 Sep 2020 11:03:49
	System	08 Sep 2020 11:03:49

US3352015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-08T07:03:43', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'a114b919-f8f8-490e-98f0-f9dc61e838a9' User entered 'No (N)'	System	08 Sep 2020 11:03:49
	System	08 Sep 2020 11:03:49

US3352015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:10:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-08T07:03:45', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'a114b919-f8f8-490e-98f0-f9dc61e838a9' User entered '08 Sep 2020 07:03'	System	08 Sep 2020 11:03:49
	System	08 Sep 2020 11:03:49

US3352015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:10:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 19:17:46

US3352015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:10:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 19:17:46

US3352015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
Data entry locked.	System	03 Sep 2020 19:17:46
User entered 'Day 6'	System	03 Sep 2020 19:17:46

US3352015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:10:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-08T22:07:39', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '346e2f5e-4b7f-4079-88a2-8e7eaf4010f8' User entered 'Yes (Y)'	System	09 Sep 2020 02:07:54
	System	09 Sep 2020 02:07:54

US3352015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:10:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-08T22:07:44', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '346e2f5e-4b7f-4079-88a2-8e7eaf4010f8' User entered '97.5'	System	09 Sep 2020 02:07:54
	System	09 Sep 2020 02:07:54

US3352015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-08T22:07:49', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '346e2f5e-4b7f-4079-88a2-8e7eaf4010f8'	System	09 Sep 2020 02:07:54
User entered 'No (N)'	System	09 Sep 2020 02:07:54

US3352015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:10:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-08T22:07:51', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '346e2f5e-4b7f-4079-88a2-8e7eaf4010f8' User entered '08 Sep 2020 22:07'	System	09 Sep 2020 02:07:54
	System	09 Sep 2020 02:07:54

US3352015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:10:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 19:17:46

US3352015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:10:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 19:17:46

US3352015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
Data entry locked.	System	03 Sep 2020 19:17:46
User entered 'Day 7'	System	03 Sep 2020 19:17:46

US3352015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:10:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-09T12:21:13', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '1cae5d58-0441-4c83-a2de-5131442ed7e9' User entered 'Yes (Y)'	System	09 Sep 2020 16:21:24
	System	09 Sep 2020 16:21:24

US3352015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:10:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-09T12:21:17', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '1cae5d58-0441-4c83-a2de-5131442ed7e9' User entered '97.8'	System	09 Sep 2020 16:21:24
	System	09 Sep 2020 16:21:24

US3352015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-09T12:21:19', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '1cae5d58-0441-4c83-a2de-5131442ed7e9'	System	09 Sep 2020 16:21:24
User entered 'No (N)'	System	09 Sep 2020 16:21:24

US3352015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:10:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-09T12:21:22', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '1cae5d58-0441-4c83-a2de-5131442ed7e9' User entered '09 Sep 2020 12:21'	System	09 Sep 2020 16:21:24
	System	09 Sep 2020 16:21:24

US3352015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:10:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 19:17:46

US3352015

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:10:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 19:17:46

US3352015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
Data entry locked.	System	03 Sep 2020 19:17:46
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 19:17:46

US3352015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:10:26

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 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-03T15:38:20', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'b15d8417-9557-48a0-822a-b2eb84546a49'	System	03 Sep 2020 19:39:04
User entered 'None (1)'	System	03 Sep 2020 19:39:04

US3352015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:10:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-03T15:38:35', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'b15d8417-9557-48a0-822a-b2eb84546a49' User entered 'No (N)'	System	03 Sep 2020 19:39:04
	System	03 Sep 2020 19:39:04

US3352015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-03T15:38:38', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'b15d8417-9557-48a0-822a-b2eb84546a49' User entered 'No (N)'	System	03 Sep 2020 19:39:04
	System	03 Sep 2020 19:39:04

US3352015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:10:26

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 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-03T15:38:42', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'b15d8417-9557-48a0-822a-b2eb84546a49'	System	03 Sep 2020 19:39:04
User entered 'None (1)'	System	03 Sep 2020 19:39:04

US3352015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:10:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-03T15:38:59', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'b15d8417-9557-48a0-822a-b2eb84546a49' User entered '03 Sep 2020 15:38'	System	03 Sep 2020 19:39:04
	System	03 Sep 2020 19:39:04

US3352015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:10:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '03 Sep 2020 15:30'	System	03 Sep 2020 19:17:46

US3352015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:10:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '03 Sep 2020 18:00'	System	03 Sep 2020 19:17:46

US3352015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
Data entry locked.	System	03 Sep 2020 19:17:46
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 19:17:46

US3352015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:10:26

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 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-03T19:38:12', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'ccabbe42-bb1b-45de-8fdf-16ec52bdf2e1' User entered 'None (1)'	System	03 Sep 2020 23:38:28
	System	03 Sep 2020 23:38:28

US3352015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:10:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-03T19:38:15', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'ccabbe42-bb1b-45de-8fdf-16ec52bdf2e1' User entered 'No (N)'	System	03 Sep 2020 23:38:28
	System	03 Sep 2020 23:38:28

US3352015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-03T19:38:18', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'ccabbe42-bb1b-45de-8fdf-16ec52bdf2e1' User entered 'No (N)'	System	03 Sep 2020 23:38:28
	System	03 Sep 2020 23:38:28

US3352015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:10:26

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 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-03T19:38:23', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'ccabbe42-bb1b-45de-8fdf-16ec52bdf2e1' User entered 'None (1)'	System	03 Sep 2020 23:38:28
	System	03 Sep 2020 23:38:28

US3352015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:10:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-03T19:38:26', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'ccabbe42-bb1b-45de-8fdf-16ec52bdf2e1' User entered '03 Sep 2020 19:38'	System	03 Sep 2020 23:38:28
	System	03 Sep 2020 23:38:28

US3352015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:10:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '03 Sep 2020 18:55'	System	03 Sep 2020 19:17:46

US3352015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:10:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 19:17:46

US3352015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
Data entry locked.	System	03 Sep 2020 19:17:46
User entered 'Day 2'	System	03 Sep 2020 19:17:46

US3352015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:10:26

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 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-04T12:22:22', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '127fc326-1989-421b-a7e3-d998db71a65d'	System	04 Sep 2020 16:23:03
User entered 'Does not interfere with activity (2)'	System	04 Sep 2020 16:23:03

US3352015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-04T12:22:26', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '127fc326-1989-421b-a7e3-d998db71a65d' User entered 'No (N)'	System	04 Sep 2020 16:23:03
	System	04 Sep 2020 16:23:03

US3352015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-04T12:22:38', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '127fc326-1989-421b-a7e3-d998db71a65d' User entered 'Yes (Y)'	System	04 Sep 2020 16:23:03
	System	04 Sep 2020 16:23:03

US3352015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:10:26

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 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-04T12:22:45', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '127fc326-1989-421b-a7e3-d998db71a65d' User entered '40'	System	04 Sep 2020 16:23:03
	System	04 Sep 2020 16:23:03

US3352015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:10:26

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 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-04T12:22:48', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '127fc326-1989-421b-a7e3-d998db71a65d' User entered 'None (1)'	System	04 Sep 2020 16:23:03
	System	04 Sep 2020 16:23:03

US3352015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:10:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-04T12:22:59', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '127fc326-1989-421b-a7e3-d998db71a65d' User entered '04 Sep 2020 12:22'	System	04 Sep 2020 16:23:03
	System	04 Sep 2020 16:23:03

US3352015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:10:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 19:17:46

US3352015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:10:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 19:17:46

US3352015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
Data entry locked.	System	03 Sep 2020 19:17:46
User entered 'Day 3'	System	03 Sep 2020 19:17:46

US3352015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:10:26

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 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-05T12:23:52', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'faafe993-6a75-4ad6-92f5-9a3ab0d3df99'	System	05 Sep 2020 16:24:24
User entered 'Does not interfere with activity (2)'	System	05 Sep 2020 16:24:24

US3352015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:10:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-05T12:23:55', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'faafe993-6a75-4ad6-92f5-9a3ab0d3df99' User entered 'Yes (Y)'	System	05 Sep 2020 16:24:24
	System	05 Sep 2020 16:24:24

US3352015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:10:26

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 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-05T12:24:00', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'faafe993-6a75-4ad6-92f5-9a3ab0d3df99' User entered '50'	System	05 Sep 2020 16:24:24
	System	05 Sep 2020 16:24:24

US3352015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-05T12:24:04', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'faafe993-6a75-4ad6-92f5-9a3ab0d3df99'	System	05 Sep 2020 16:24:24
User entered 'Yes (Y)'	System	05 Sep 2020 16:24:24

US3352015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:10:26

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 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-05T12:24:09', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'faafe993-6a75-4ad6-92f5-9a3ab0d3df99' User entered '60'	System	05 Sep 2020 16:24:24
	System	05 Sep 2020 16:24:24

US3352015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:10:26

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 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-05T12:24:18', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'faafe993-6a75-4ad6-92f5-9a3ab0d3df99'	System	05 Sep 2020 16:24:24
User entered 'None (1)'	System	05 Sep 2020 16:24:24

US3352015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:10:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-05T12:24:22', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'faafe993-6a75-4ad6-92f5-9a3ab0d3df99' User entered '05 Sep 2020 12:24'	System	05 Sep 2020 16:24:24
	System	05 Sep 2020 16:24:24

US3352015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:10:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 19:17:46

US3352015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:10:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 19:17:46

US3352015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
Data entry locked.	System	03 Sep 2020 19:17:46
User entered 'Day 4'	System	03 Sep 2020 19:17:46

US3352015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:10:26

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 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-06T13:44:10', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'b898dd0a-e74b-46b9-8b18-c1ccb0391971' User entered 'None (1)'	System	06 Sep 2020 17:44:23
	System	06 Sep 2020 17:44:23

US3352015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:10:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-06T13:44:13', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'b898dd0a-e74b-46b9-8b18-c1ccb0391971' User entered 'No (N)'	System	06 Sep 2020 17:44:23
	System	06 Sep 2020 17:44:23

US3352015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-06T13:44:16', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'b898dd0a-e74b-46b9-8b18-c1ccb0391971' User entered 'No (N)'	System	06 Sep 2020 17:44:23
	System	06 Sep 2020 17:44:23

US3352015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:10:26

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 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-06T13:44:18', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'b898dd0a-e74b-46b9-8b18-c1ccb0391971' User entered 'None (1)'	System	06 Sep 2020 17:44:23
	System	06 Sep 2020 17:44:23

US3352015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:10:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-06T13:44:20', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'b898dd0a-e74b-46b9-8b18-c1ccb0391971' User entered '06 Sep 2020 13:44'	System	06 Sep 2020 17:44:23
	System	06 Sep 2020 17:44:23

US3352015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:10:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 19:17:46

US3352015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:10:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 19:17:46

US3352015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
Data entry locked.	System	03 Sep 2020 19:17:46
User entered 'Day 5'	System	03 Sep 2020 19:17:46

US3352015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:10:26

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 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-08T07:03:59', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'db8b67aa-0729-41d7-b948-bee1e0153345'	System	08 Sep 2020 11:04:11
User entered 'None (1)'	System	08 Sep 2020 11:04:11

US3352015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:10:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-08T07:03:57', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'db8b67aa-0729-41d7-b948-bee1e0153345' User entered 'No (N)'	System	08 Sep 2020 11:04:11
	System	08 Sep 2020 11:04:11

US3352015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-08T07:03:57', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'db8b67aa-0729-41d7-b948-bee1e0153345' User entered 'No (N)'	System	08 Sep 2020 11:04:11
	System	08 Sep 2020 11:04:11

US3352015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:10:26

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 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-08T07:04:04', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'db8b67aa-0729-41d7-b948-bee1e0153345'	System	08 Sep 2020 11:04:11
User entered 'None (1)'	System	08 Sep 2020 11:04:11

US3352015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:10:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-08T07:04:08', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'db8b67aa-0729-41d7-b948-bee1e0153345' User entered '08 Sep 2020 07:04'	System	08 Sep 2020 11:04:11
	System	08 Sep 2020 11:04:11

US3352015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:10:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 19:17:46

US3352015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:10:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 19:17:46

US3352015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
Data entry locked.	System	03 Sep 2020 19:17:46
User entered 'Day 6'	System	03 Sep 2020 19:17:46

US3352015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:10:26

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 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-08T22:07:57', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '89f0101d-7f73-4df7-8499-02406f5ca205'	System	09 Sep 2020 02:08:08
User entered 'None (1)'	System	09 Sep 2020 02:08:08

US3352015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:10:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-08T22:07:59', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '89f0101d-7f73-4df7-8499-02406f5ca205' User entered 'No (N)'	System	09 Sep 2020 02:08:08
	System	09 Sep 2020 02:08:08

US3352015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-08T22:08:02', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '89f0101d-7f73-4df7-8499-02406f5ca205' User entered 'No (N)'	System	09 Sep 2020 02:08:08
	System	09 Sep 2020 02:08:08

US3352015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:10:26

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 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-08T22:08:04', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '89f0101d-7f73-4df7-8499-02406f5ca205'	System	09 Sep 2020 02:08:08
User entered 'None (1)'	System	09 Sep 2020 02:08:08

US3352015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:10:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-08T22:08:06', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '89f0101d-7f73-4df7-8499-02406f5ca205' User entered '08 Sep 2020 22:08'	System	09 Sep 2020 02:08:08
	System	09 Sep 2020 02:08:08

US3352015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:10:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 19:17:46

US3352015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:10:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 19:17:46

US3352015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
Data entry locked.	System	03 Sep 2020 19:17:46
User entered 'Day 7'	System	03 Sep 2020 19:17:46

US3352015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:10:26

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 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-09T12:21:26', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'e4f50604-f0e0-4746-9677-acc3c14fe8af' User entered 'None (1)'	System	09 Sep 2020 16:21:39
	System	09 Sep 2020 16:21:39

US3352015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:10:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-09T12:21:29', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'e4f50604-f0e0-4746-9677-acc3c14fe8af' User entered 'No (N)'	System	09 Sep 2020 16:21:39
	System	09 Sep 2020 16:21:39

US3352015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-09T12:21:32', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'e4f50604-f0e0-4746-9677-acc3c14fe8af' User entered 'No (N)'	System	09 Sep 2020 16:21:39
	System	09 Sep 2020 16:21:39

US3352015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:10:26

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 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-09T12:21:34', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'e4f50604-f0e0-4746-9677-acc3c14fe8af' User entered 'None (1)'	System	09 Sep 2020 16:21:39
	System	09 Sep 2020 16:21:39

US3352015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:10:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-09T12:21:36', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'e4f50604-f0e0-4746-9677-acc3c14fe8af' User entered '09 Sep 2020 12:21'	System	09 Sep 2020 16:21:39
	System	09 Sep 2020 16:21:39

US3352015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:10:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 19:17:46

US3352015

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:10:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 19:17:46

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
Data entry locked.	System	03 Sep 2020 19:17:46
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 19:17:46

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-03T15:39:03', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'cf965869-e2b0-4cd9-a216-9c8912722ea2' User entered 'None (0)'	System	03 Sep 2020 19:39:36
	System	03 Sep 2020 19:39:36

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-03T15:39:07', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'cf965869-e2b0-4cd9-a216-9c8912722ea2' User entered 'None (0)'	System	03 Sep 2020 19:39:36
	System	03 Sep 2020 19:39:36

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-03T15:39:09', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'cf965869-e2b0-4cd9-a216-9c8912722ea2' User entered 'None (0)'	System	03 Sep 2020 19:39:36
	System	03 Sep 2020 19:39:36

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-03T15:39:12', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'cf965869-e2b0-4cd9-a216-9c8912722ea2' User entered 'None (0)'	System	03 Sep 2020 19:39:36
	System	03 Sep 2020 19:39:36

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-03T15:39:13', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'cf965869-e2b0-4cd9-a216-9c8912722ea2' User entered 'None (0)'	System	03 Sep 2020 19:39:36
	System	03 Sep 2020 19:39:36

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-03T15:39:20', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'cf965869-e2b0-4cd9-a216-9c8912722ea2' User entered 'None (0)'	System	03 Sep 2020 19:39:36
	System	03 Sep 2020 19:39:36

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:26

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 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-03T15:39:23', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'cf965869-e2b0-4cd9-a216-9c8912722ea2' User entered 'No (N)'	System	03 Sep 2020 19:39:36
	System	03 Sep 2020 19:39:36

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-03T15:39:32', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'cf965869-e2b0-4cd9-a216-9c8912722ea2' User entered '03 Sep 2020 15:39'	System	03 Sep 2020 19:39:36
	System	03 Sep 2020 19:39:36

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '03 Sep 2020 15:30'	System	03 Sep 2020 19:17:46

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:10:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '03 Sep 2020 18:00'	System	03 Sep 2020 19:17:46

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
Data entry locked.	System	03 Sep 2020 19:17:46
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 19:17:46

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-03T19:38:29', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '50363edc-dfbf-4f4c-b568-efdf9b3d3ec0' User entered 'None (0)'	System	03 Sep 2020 23:38:58
	System	03 Sep 2020 23:38:58

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-03T19:38:31', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '50363edc-dfbf-4f4c-b568-efdf9b3d3ec0' User entered 'None (0)'	System	03 Sep 2020 23:38:58
	System	03 Sep 2020 23:38:58

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-03T19:38:33', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '50363edc-dfbf-4f4c-b568-efdf9b3d3ec0' User entered 'None (0)'	System	03 Sep 2020 23:38:58
	System	03 Sep 2020 23:38:58

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-03T19:38:36', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '50363edc-dfbf-4f4c-b568-efdf9b3d3ec0' User entered 'None (0)'	System	03 Sep 2020 23:38:58
	System	03 Sep 2020 23:38:58

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-03T19:38:38', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '50363edc-dfbf-4f4c-b568-efdf9b3d3ec0' User entered 'None (0)'	System	03 Sep 2020 23:38:58
	System	03 Sep 2020 23:38:58

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-03T19:38:49', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '50363edc-dfbf-4f4c-b568-efdf9b3d3ec0' User entered 'None (0)'	System	03 Sep 2020 23:38:58
	System	03 Sep 2020 23:38:58

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:26

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 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-03T19:38:53', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '50363edc-dfbf-4f4c-b568-efdf9b3d3ec0' User entered 'No (N)'	System	03 Sep 2020 23:38:58
	System	03 Sep 2020 23:38:58

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-03T19:38:55', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '50363edc-dfbf-4f4c-b568-efdf9b3d3ec0' User entered '03 Sep 2020 19:38'	System	03 Sep 2020 23:38:58
	System	03 Sep 2020 23:38:58

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '03 Sep 2020 18:55'	System	03 Sep 2020 19:17:46

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:10:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 19:17:46

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
Data entry locked.	System	03 Sep 2020 19:17:46
User entered 'Day 2'	System	03 Sep 2020 19:17:46

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-04T12:23:03', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'ceb34bf2-3426-4603-9732-fd70425f43e5' User entered 'None (0)'	System	04 Sep 2020 16:23:49
	System	04 Sep 2020 16:23:49

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-04T12:23:07', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'ceb34bf2-3426-4603-9732-fd70425f43e5'	System	04 Sep 2020 16:23:49
User entered 'Some interference with activity (2)'	System	04 Sep 2020 16:23:49

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-04T12:23:09', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'ceb34bf2-3426-4603-9732-fd70425f43e5' User entered 'None (0)'	System	04 Sep 2020 16:23:49
	System	04 Sep 2020 16:23:49

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-04T12:23:20', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'ceb34bf2-3426-4603-9732-fd70425f43e5' User entered 'None (0)'	System	04 Sep 2020 16:23:49
	System	04 Sep 2020 16:23:49

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-04T12:23:23', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'ceb34bf2-3426-4603-9732-fd70425f43e5' User entered 'None (0)'	System	04 Sep 2020 16:23:49
	System	04 Sep 2020 16:23:49

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-04T12:23:25', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'ceb34bf2-3426-4603-9732-fd70425f43e5' User entered 'None (0)'	System	04 Sep 2020 16:23:49
	System	04 Sep 2020 16:23:49

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:26

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 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-04T12:23:31', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'ceb34bf2-3426-4603-9732-fd70425f43e5' User entered 'Yes (Y)'	System	04 Sep 2020 16:23:49
	System	04 Sep 2020 16:23:49

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-04T12:23:43', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'ceb34bf2-3426-4603-9732-fd70425f43e5' User entered '04 Sep 2020 12:23'	System	04 Sep 2020 16:23:49
	System	04 Sep 2020 16:23:49

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 19:17:46

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:10:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 19:17:46

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
Data entry locked.	System	03 Sep 2020 19:17:46
User entered 'Day 3'	System	03 Sep 2020 19:17:46

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-05T12:24:25', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '1aeb1483-8cbb-4959-9f73-9342c1422808' User entered 'None (0)'	System	05 Sep 2020 16:24:42
	System	05 Sep 2020 16:24:42

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-05T12:24:27', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '1aeb1483-8cbb-4959-9f73-9342c1422808'	System	05 Sep 2020 16:24:42
User entered 'No interference with activity (1)'	System	05 Sep 2020 16:24:42

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-05T12:24:29', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '1aeb1483-8cbb-4959-9f73-9342c1422808' User entered 'None (0)'	System	05 Sep 2020 16:24:42
	System	05 Sep 2020 16:24:42

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-05T12:24:31', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '1aeb1483-8cbb-4959-9f73-9342c1422808' User entered 'None (0)'	System	05 Sep 2020 16:24:42
	System	05 Sep 2020 16:24:42

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-05T12:24:33', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '1aeb1483-8cbb-4959-9f73-9342c1422808' User entered 'None (0)'	System	05 Sep 2020 16:24:42
	System	05 Sep 2020 16:24:42

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-05T12:24:35', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '1aeb1483-8cbb-4959-9f73-9342c1422808' User entered 'None (0)'	System	05 Sep 2020 16:24:42
	System	05 Sep 2020 16:24:42

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:26

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 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-05T12:24:37', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '1aeb1483-8cbb-4959-9f73-9342c1422808' User entered 'No (N)'	System	05 Sep 2020 16:24:42
	System	05 Sep 2020 16:24:42

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-05T12:24:39', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '1aeb1483-8cbb-4959-9f73-9342c1422808' User entered '05 Sep 2020 12:24'	System	05 Sep 2020 16:24:42
	System	05 Sep 2020 16:24:42

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 19:17:46

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:10:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 19:17:46

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
Data entry locked.	System	03 Sep 2020 19:17:46
User entered 'Day 4'	System	03 Sep 2020 19:17:46

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-06T13:44:24', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '9006faa0-0b41-4d9d-a976-e0c96a1ed7e7' User entered 'None (0)'	System	06 Sep 2020 17:44:48
	System	06 Sep 2020 17:44:48

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-06T13:44:27', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '9006faa0-0b41-4d9d-a976-e0c96a1ed7e7'	System	06 Sep 2020 17:44:48
User entered 'No interference with activity (1)'	System	06 Sep 2020 17:44:48

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-06T13:44:32', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '9006faa0-0b41-4d9d-a976-e0c96a1ed7e7' User entered 'None (0)'	System	06 Sep 2020 17:44:48
	System	06 Sep 2020 17:44:48

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-06T13:44:34', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '9006faa0-0b41-4d9d-a976-e0c96a1ed7e7' User entered 'None (0)'	System	06 Sep 2020 17:44:48
	System	06 Sep 2020 17:44:48

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-06T13:44:37', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '9006faa0-0b41-4d9d-a976-e0c96a1ed7e7'	System	06 Sep 2020 17:44:48
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	06 Sep 2020 17:44:48

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-06T13:44:39', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '9006faa0-0b41-4d9d-a976-e0c96a1ed7e7' User entered 'None (0)'	System	06 Sep 2020 17:44:48
	System	06 Sep 2020 17:44:48

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:26

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 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-06T13:44:42', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '9006faa0-0b41-4d9d-a976-e0c96a1ed7e7' User entered 'No (N)'	System	06 Sep 2020 17:44:48
	System	06 Sep 2020 17:44:48

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-06T13:44:44', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '9006faa0-0b41-4d9d-a976-e0c96a1ed7e7' User entered '06 Sep 2020 13:44'	System	06 Sep 2020 17:44:48
	System	06 Sep 2020 17:44:48

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 19:17:46

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:10:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 19:17:46

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
Data entry locked.	System	03 Sep 2020 19:17:46
User entered 'Day 5'	System	03 Sep 2020 19:17:46

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-08T07:04:12', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'd23af83c-aa88-4fff-93fb-58971ca94a5b'	System	08 Sep 2020 11:04:34
User entered 'No interference with activity (1)'	System	08 Sep 2020 11:04:34

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-08T07:04:14', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'd23af83c-aa88-4fff-93fb-58971ca94a5b' User entered 'None (0)'	System	08 Sep 2020 11:04:34
	System	08 Sep 2020 11:04:34

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-08T07:04:16', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'd23af83c-aa88-4fff-93fb-58971ca94a5b' User entered 'None (0)'	System	08 Sep 2020 11:04:34
	System	08 Sep 2020 11:04:34

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-08T07:04:19', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'd23af83c-aa88-4fff-93fb-58971ca94a5b' User entered 'None (0)'	System	08 Sep 2020 11:04:34
	System	08 Sep 2020 11:04:34

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-08T07:04:21', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'd23af83c-aa88-4fff-93fb-58971ca94a5b' User entered 'None (0)'	System	08 Sep 2020 11:04:34
	System	08 Sep 2020 11:04:34

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-08T07:04:24', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'd23af83c-aa88-4fff-93fb-58971ca94a5b' User entered 'None (0)'	System	08 Sep 2020 11:04:34
	System	08 Sep 2020 11:04:34

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:26

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 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-08T07:04:29', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'd23af83c-aa88-4fff-93fb-58971ca94a5b' User entered 'No (N)'	System	08 Sep 2020 11:04:34
	System	08 Sep 2020 11:04:34

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-08T07:04:32', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'd23af83c-aa88-4fff-93fb-58971ca94a5b' User entered '08 Sep 2020 07:04'	System	08 Sep 2020 11:04:34
	System	08 Sep 2020 11:04:34

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 19:17:46

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:10:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 19:17:46

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
Data entry locked.	System	03 Sep 2020 19:17:46
User entered 'Day 6'	System	03 Sep 2020 19:17:46

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-08T22:08:10', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '256df04a-6762-4866-beb8-4e81d29da5ae' User entered 'None (0)'	System	09 Sep 2020 02:08:28
	System	09 Sep 2020 02:08:28

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-08T22:08:13', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '256df04a-6762-4866-beb8-4e81d29da5ae' User entered 'None (0)'	System	09 Sep 2020 02:08:28
	System	09 Sep 2020 02:08:28

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-08T22:08:15', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '256df04a-6762-4866-beb8-4e81d29da5ae' User entered 'None (0)'	System	09 Sep 2020 02:08:28
	System	09 Sep 2020 02:08:28

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-08T22:08:17', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '256df04a-6762-4866-beb8-4e81d29da5ae' User entered 'None (0)'	System	09 Sep 2020 02:08:28
	System	09 Sep 2020 02:08:28

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-08T22:08:18', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '256df04a-6762-4866-beb8-4e81d29da5ae' User entered 'None (0)'	System	09 Sep 2020 02:08:28
	System	09 Sep 2020 02:08:28

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-08T22:08:20', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '256df04a-6762-4866-beb8-4e81d29da5ae' User entered 'None (0)'	System	09 Sep 2020 02:08:28
	System	09 Sep 2020 02:08:28

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:26

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 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-08T22:08:22', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '256df04a-6762-4866-beb8-4e81d29da5ae' User entered 'No (N)'	System	09 Sep 2020 02:08:28
	System	09 Sep 2020 02:08:28

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-08T22:08:24', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '256df04a-6762-4866-beb8-4e81d29da5ae' User entered '08 Sep 2020 22:08'	System	09 Sep 2020 02:08:28
	System	09 Sep 2020 02:08:28

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 19:17:46

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:10:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 19:17:46

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
Data entry locked.	System	03 Sep 2020 19:17:46
User entered 'Day 7'	System	03 Sep 2020 19:17:46

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-09T12:21:39', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '9e725957-e39f-44f4-abd5-364ca8b573dd' User entered 'None (0)'	System	09 Sep 2020 16:21:54
	System	09 Sep 2020 16:21:54

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-09T12:21:40', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '9e725957-e39f-44f4-abd5-364ca8b573dd' User entered 'None (0)'	System	09 Sep 2020 16:21:54
	System	09 Sep 2020 16:21:54

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-09T12:21:41', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '9e725957-e39f-44f4-abd5-364ca8b573dd' User entered 'None (0)'	System	09 Sep 2020 16:21:54
	System	09 Sep 2020 16:21:54

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-09T12:21:42', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '9e725957-e39f-44f4-abd5-364ca8b573dd' User entered 'None (0)'	System	09 Sep 2020 16:21:54
	System	09 Sep 2020 16:21:54

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-09T12:21:43', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '9e725957-e39f-44f4-abd5-364ca8b573dd' User entered 'None (0)'	System	09 Sep 2020 16:21:54
	System	09 Sep 2020 16:21:54

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-09T12:21:45', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '9e725957-e39f-44f4-abd5-364ca8b573dd' User entered 'None (0)'	System	09 Sep 2020 16:21:54
	System	09 Sep 2020 16:21:54

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:26

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 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-09T12:21:47', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '9e725957-e39f-44f4-abd5-364ca8b573dd' User entered 'No (N)'	System	09 Sep 2020 16:21:54
	System	09 Sep 2020 16:21:54

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-09-09T12:21:49', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '9e725957-e39f-44f4-abd5-364ca8b573dd' User entered '09 Sep 2020 12:21'	System	09 Sep 2020 16:21:54
	System	09 Sep 2020 16:21:54

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 19:17:46

US3352015

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:10:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 19:17:46

US3352015

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:57:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Yes (Y)'	Rosaidaliz Carreira (b) (4)	11 Sep 2020 16:51:32

US3352015

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:57:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '11 Sep 2020'	Rosaidaliz Carreira (b) (4)	11 Sep 2020 16:51:32

US3352015

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:57:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Contact Made (CONTACT MADE)'	Rosaidaliz Carreira (b) (4)	11 Sep 2020 16:51:32

US3352015

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:57:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered empty.	Rosaidaliz Carreira (b) (4)	11 Sep 2020 16:51:32

US3352015

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:57:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Yes (Y)'	Rosaidaliz Carreira (b) (4)	11 Sep 2020 16:51:41

US3352015

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:57:29
User entered 'I'	System	11 Sep 2020 16:51:41

US3352015

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:18
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4)	15 Sep 2020 14:49:23

US3352015

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:26

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:18
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User closed query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	14 Oct 2020 07:27:04
Query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'DAY 43 SAFETY CALL WAS COMPLETED 2 DAYS OUT OF WINDOW. DEVIATION HAD BEEN DOCUMENTED.' (Site from System).	Rosaidaliz Carreira (b) (4)	13 Oct 2020 18:15:13
User opened query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	15 Sep 2020 14:49:23
User entered '15 Sep 2020'	Yulexis Amestoy (b) (4)	15 Sep 2020 14:49:23

US3352015

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:18
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Contact Made (CONTACT MADE)'	Yulexis Amestoy (b) (4)	15 Sep 2020 14:49:23

US3352015

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:18
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered empty.	Yulexis Amestoy (b) (4)	15 Sep 2020 14:49:23

US3352015

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:18
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4)	15 Sep 2020 14:49:28

US3352015

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:58:18
User entered 'I'	System	15 Sep 2020 14:49:28

US3352015

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:23:26
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Sep 2020 20:03:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Sep 2020 20:03:03
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 20:03:03
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 19:33:22
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	23 Sep 2020 19:33:22
User entered empty; reason for change Data Entry Error	Yulexis Amestoy (b) (4)	23 Sep 2020 19:33:22
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	23 Sep 2020 19:25:16
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4)	23 Sep 2020 19:24:15

US3352015

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:26

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:23:26
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '24 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 20:03:03
User closed query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	23 Sep 2020 19:33:22
Query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	23 Sep 2020 19:33:22
User entered empty; reason for change Data Entry Error	Yulexis Amestoy (b) (4)	23 Sep 2020 19:33:22
User opened query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	23 Sep 2020 19:24:15
User entered '23 Sep 2020'	Yulexis Amestoy (b) (4)	23 Sep 2020 19:24:15

US3352015

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:23:26
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Sep 2020 20:03:03
User entered empty; reason for change Data Entry Error	Yulexis Amestoy (b) (4)	23 Sep 2020 19:25:16
User entered 'Contact Made (CONTACT MADE)'	Yulexis Amestoy (b) (4)	23 Sep 2020 19:24:15

US3352015

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:23:26
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered empty.	Yulexis Amestoy (b) (4)	23 Sep 2020 19:24:15

US3352015

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:23:26
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 20:03:20

US3352015

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:23:26
User entered 'I'	System	24 Sep 2020 20:03:20

US3352015

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:10:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:41
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Yes (Y)'	Wanda Delgado (b) (4)	01 Oct 2020 17:55:53

US3352015

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:10:26

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:41
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User closed query 'Per CDM: Please consider updating the date format to DD-MM-YYYY, including 2 digits for day (for example 01-JAN-2020). Thank you!' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 08:13:05
Query 'Per CDM: Please consider updating the date format to DD-MM-YYYY, including 2 digits for day (for example 01-JAN-2020). Thank you!' answered with 'updated' (Site from DM).	Matthew Muniz (b) (4)	05 Nov 2020 13:29:12
User entered '01 Oct 2020' reason for change: Data Entry Error	Matthew Muniz (b) (4)	05 Nov 2020 13:29:02
User opened query 'Per CDM: Please consider updating the date format to DD-MM-YYYY, including 2 digits for day (for example 01-JAN-2020). Thank you!' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 08:40:01
User entered '1 Oct 2020'	Wanda Delgado (b) (4)	01 Oct 2020 17:55:53

US3352015

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:41
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Clinic (Clinic)'	Wanda Delgado (b) (4)	01 Oct 2020 17:55:53

US3352015

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:10:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:41
User entered 'VISIT3'	System	01 Oct 2020 17:55:53

US3352015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:26

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:41
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Yes (Y)'	Wanda Delgado (b) (4)	01 Oct 2020 17:56:57

US3352015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:26

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:41
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User closed query 'Per CDM: Please consider updating the date format to DD-MM-YYYY, including 2 digits for day (for example 01-JAN-2020). Thank you!' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 06:20:53
Query 'Per CDM: Please consider updating the date format to DD-MM-YYYY, including 2 digits for day (for example 01-JAN-2020). Thank you!' answered with 'updated' (Site from DM).	Matthew Muniz (b) (4)	06 Nov 2020 13:36:58
User entered '01 Oct 2020' reason for change: Data Entry Error	Matthew Muniz (b) (4)	06 Nov 2020 13:36:53
User opened query 'Per CDM: Please consider updating the date format to DD-MM-YYYY, including 2 digits for day (for example 01-JAN-2020). Thank you!' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 08:13:12
User entered '1 Oct 2020'	Wanda Delgado (b) (4)	01 Oct 2020 17:56:57

US3352015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:41
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '13:05'	Wanda Delgado (b) (4)	01 Oct 2020 17:56:57

US3352015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:41
User entered '01 Oct 2020 13:05'	System	06 Nov 2020 13:36:53
User entered '1 Oct 2020 13:05'	System	01 Oct 2020 17:56:57

US3352015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:41
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '36.5' C	Wanda Delgado (b) (4)	01 Oct 2020 17:56:57

US3352015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:41
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User closed query 'Data is required. Please provide.' (Site from System).	System	01 Oct 2020 17:57:03
Query 'Data is required. Please provide.' answered by System data change (Site from System).		01 Oct 2020 17:57:03
User entered 'Oral (Oral)' reason for change: Data Entry Error	Wanda Delgado (b) (4)	01 Oct 2020 17:57:03
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Oct 2020 17:56:57
User entered empty.	Wanda Delgado (b) (4)	01 Oct 2020 17:56:57

US3352015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:41
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered empty.	Wanda Delgado (b) (4)	01 Oct 2020 17:56:57

US3352015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:41
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '76'	Wanda Delgado (b) (4)	01 Oct 2020 17:56:57

US3352015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:41
User entered 'bpm'	System	01 Oct 2020 17:56:57

US3352015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:41
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '14'	Wanda Delgado (b) (4)	01 Oct 2020 17:56:57

US3352015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:41
User entered 'breaths/min'	System	01 Oct 2020 17:56:57

US3352015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:41
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '112'	Wanda Delgado (b) (4)	01 Oct 2020 17:56:57

US3352015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:41
User entered 'mmHg'	System	01 Oct 2020 17:56:57

US3352015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:41
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '74'	Wanda Delgado (b) (4)	01 Oct 2020 17:56:57

US3352015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:41
User entered 'mmHg'	System	01 Oct 2020 17:56:57

US3352015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:26

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:41

US3352015

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:26

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:41

US3352015

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:10:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:41
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'No (N)'	Wanda Delgado (b) (4)	01 Oct 2020 17:57:12

US3352015

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:10:26

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:41
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered empty.	Wanda Delgado (b) (4)	01 Oct 2020 17:57:12

US3352015

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:41
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Yes (Y)'	Wanda Delgado (b) (4)	01 Oct 2020 17:57:32

US3352015

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:26

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:41
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '01 Oct 2020' reason for change: Data Entry Error	Matthew Muniz (b) (4)	06 Nov 2020 13:37:04
User entered '1 Oct 2020'	Wanda Delgado (b) (4)	01 Oct 2020 17:57:32

US3352015

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:26

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:41
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '13:27'	Wanda Delgado (b) (4)	01 Oct 2020 17:57:32

US3352015

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:26

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:41
User entered '01 Oct 2020 13:27'	System	06 Nov 2020 13:37:04
User entered '1 Oct 2020 13:27'	System	01 Oct 2020 17:57:32

US3352015

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:41
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Yes (Y)'	Wanda Delgado (b) (4)	01 Oct 2020 17:57:37

US3352015

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:00:41
User entered 'I'	System	01 Oct 2020 17:57:37

US3352015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
Data entry locked.	System	04 Aug 2020 20:45:19
User entered 'Day 64'	System	04 Aug 2020 20:45:19

US3352015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[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 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-10-07T14:09:40', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '8bf03101-b10f-4177-b04d-e83a35e69784' User entered 'No (N)'	System	07 Oct 2020 18:09:58
	System	07 Oct 2020 18:09:58

US3352015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

Have you been exposed to someone with 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 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-10-07T14:09:51', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '8bf03101-b10f-4177-b04d-e83a35e69784'	System	07 Oct 2020 18:09:58
User entered 'No (N)'	System	07 Oct 2020 18:09:58

US3352015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-10-07T14:09:56', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '8bf03101-b10f-4177-b04d-e83a35e69784' User entered '07 Oct 2020 14:09:56'	System	07 Oct 2020 18:09:58
	System	07 Oct 2020 18:09:58

US3352015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
Data entry locked.	System	04 Aug 2020 20:45:19
User entered '04 Oct 2020 00:01'	System	04 Aug 2020 20:45:19

US3352015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
Data entry locked.	System	04 Aug 2020 20:45:19
User entered '08 Oct 2020 23:59'	System	04 Aug 2020 20:45:19

US3352015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
Data entry locked.	System	04 Aug 2020 20:45:19
User entered 'Day 71'	System	04 Aug 2020 20:45:19

US3352015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[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 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-10-13T12:08:30', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '66a55c19-c1ab-410e-aa53-841ea0a9276c' User entered 'No (N)'	System	13 Oct 2020 16:08:41
	System	13 Oct 2020 16:08:41

US3352015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

Have you been exposed to someone with 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 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-10-13T12:08:34', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '66a55c19-c1ab-410e-aa53-841ea0a9276c' User entered 'No (N)'	System	13 Oct 2020 16:08:41
	System	13 Oct 2020 16:08:41

US3352015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-10-13T12:08:38', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '66a55c19-c1ab-410e-aa53-841ea0a9276c' User entered '13 Oct 2020 12:08:38'	System	13 Oct 2020 16:08:41
	System	13 Oct 2020 16:08:41

US3352015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
Data entry locked.	System	04 Aug 2020 20:45:19
User entered '11 Oct 2020 00:01'	System	04 Aug 2020 20:45:19

US3352015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
Data entry locked.	System	04 Aug 2020 20:45:19
User entered '15 Oct 2020 23:59'	System	04 Aug 2020 20:45:19

US3352015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
Data entry locked.	System	04 Aug 2020 20:45:19
User entered 'Day 78'	System	04 Aug 2020 20:45:19

US3352015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-10-20T14:23:42', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '2acb4c21-39c5-4030-9c1d-6e2dc07fd186'	System	20 Oct 2020 18:23:53
User entered 'No (N)'	System	20 Oct 2020 18:23:53

US3352015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

Have you been exposed to someone with 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 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-10-20T14:23:45', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '2acb4c21-39c5-4030-9c1d-6e2dc07fd186'	System	20 Oct 2020 18:23:53
User entered 'No (N)'	System	20 Oct 2020 18:23:53

US3352015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-10-20T14:23:49', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '2acb4c21-39c5-4030-9c1d-6e2dc07fd186' User entered '20 Oct 2020 14:23:49'	System	20 Oct 2020 18:23:53
	System	20 Oct 2020 18:23:53

US3352015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
Data entry locked.	System	04 Aug 2020 20:45:19
User entered '18 Oct 2020 00:01'	System	04 Aug 2020 20:45:19

US3352015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
Data entry locked.	System	04 Aug 2020 20:45:19
User entered '22 Oct 2020 23:59'	System	04 Aug 2020 20:45:19

US3352015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
Data entry locked.	System	04 Aug 2020 20:45:19
User entered 'Day 92'	System	04 Aug 2020 20:45:19

US3352015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[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 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-11-01T01:09:46', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '0f9aa913-5807-4208-b0b2-269e7fa07990'	System	01 Nov 2020 06:10:01
User entered 'No (N)'	System	01 Nov 2020 06:10:01

US3352015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

Have you been exposed to someone with 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 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-11-01T01:09:53', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '0f9aa913-5807-4208-b0b2-269e7fa07990'	System	01 Nov 2020 06:10:01
User entered 'No (N)'	System	01 Nov 2020 06:10:01

US3352015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-11-01T01:09:58', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '0f9aa913-5807-4208-b0b2-269e7fa07990' User entered '01 Nov 2020 01:09:58'	System	01 Nov 2020 06:10:01
	System	01 Nov 2020 06:10:01

US3352015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
Data entry locked.	System	04 Aug 2020 20:45:19
User entered '01 Nov 2020 00:01'	System	04 Aug 2020 20:45:19

US3352015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
Data entry locked.	System	04 Aug 2020 20:45:19
User entered '05 Nov 2020 23:59'	System	04 Aug 2020 20:45:19

US3352015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
Data entry locked.	System	04 Aug 2020 20:45:19
User entered 'Day 99'	System	04 Aug 2020 20:45:19

US3352015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[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 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-11-10T10:55:12', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '8da10b2a-a261-410c-81c4-625fbd14ee61' User entered 'No (N)'	System	10 Nov 2020 15:55:24
	System	10 Nov 2020 15:55:24

US3352015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

Have you been exposed to someone with 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 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-11-10T10:55:16', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '8da10b2a-a261-410c-81c4-625fbd14ee61' User entered 'No (N)'	System	10 Nov 2020 15:55:24
	System	10 Nov 2020 15:55:24

US3352015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-11-10T10:55:19', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '8da10b2a-a261-410c-81c4-625fbd14ee61' User entered '10 Nov 2020 10:55:19'	System	10 Nov 2020 15:55:24
	System	10 Nov 2020 15:55:24

US3352015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
Data entry locked.	System	04 Aug 2020 20:45:19
User entered '08 Nov 2020 00:01'	System	04 Aug 2020 20:45:19

US3352015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
Data entry locked.	System	04 Aug 2020 20:45:19
User entered '12 Nov 2020 23:59'	System	04 Aug 2020 20:45:19

US3352015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
Data entry locked.	System	04 Aug 2020 20:45:19
User entered 'Day 106'	System	04 Aug 2020 20:45:19

US3352015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[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 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-11-15T00:01:30', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '6bb130a7-5fbe-411e-b08b-ac69b1820d36'	System	15 Nov 2020 05:01:45
User entered 'No (N)'	System	15 Nov 2020 05:01:45

US3352015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

Have you been exposed to someone with 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 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-11-15T00:01:32', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '6bb130a7-5fbe-411e-b08b-ac69b1820d36'	System	15 Nov 2020 05:01:45
User entered 'No (N)'	System	15 Nov 2020 05:01:45

US3352015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-11-15T00:01:36', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '6bb130a7-5fbe-411e-b08b-ac69b1820d36' User entered '15 Nov 2020 00:01:36'	System	15 Nov 2020 05:01:45
	System	15 Nov 2020 05:01:45

US3352015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
Data entry locked.	System	04 Aug 2020 20:45:19
User entered '15 Nov 2020 00:01'	System	04 Aug 2020 20:45:19

US3352015

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:47:50
Data entry locked.	System	04 Aug 2020 20:45:19
User entered '19 Nov 2020 23:59'	System	04 Aug 2020 20:45:19

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[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 (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-11-20T16:23:50', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'f9291edc-27fb-4f23-99ab-df247751869f' User entered 'No (N)'	System	20 Nov 2020 21:24:03

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

Have you been exposed to someone with 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 (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-11-20T16:23:56', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'f9291edc-27fb-4f23-99ab-df247751869f' User entered 'No (N)'	System	20 Nov 2020 21:24:03

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-11-20T16:23:59', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'f9291edc-27fb-4f23-99ab-df247751869f' User entered '20 Nov 2020 16:23:59'	System	20 Nov 2020 21:24:03
	System	20 Nov 2020 21:24:03

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[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 (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-11-27T16:39:33', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'f5851846-5d93-4b18-a0ce-7d3821d771cc' User entered 'No (N)'	System	27 Nov 2020 21:39:46
	System	27 Nov 2020 21:39:46

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

Have you been exposed to someone with 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 (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-11-27T16:39:38', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'f5851846-5d93-4b18-a0ce-7d3821d771cc' User entered 'No (N)'	System	27 Nov 2020 21:39:46

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-11-27T16:39:42', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'f5851846-5d93-4b18-a0ce-7d3821d771cc' User entered '27 Nov 2020 16:39:42'	System	27 Nov 2020 21:39:46
	System	27 Nov 2020 21:39:46

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[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 (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-12-04T11:23:05', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '170e6447-f704-47aa-8994-82b849bc19a0' User entered 'No (N)'	System	04 Dec 2020 16:23:13
	System	04 Dec 2020 16:23:13

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

Have you been exposed to someone with 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 (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-12-04T11:23:06', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '170e6447-f704-47aa-8994-82b849bc19a0' User entered 'No (N)'	System	04 Dec 2020 16:23:13
	System	04 Dec 2020 16:23:13

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-12-04T11:23:09', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '170e6447-f704-47aa-8994-82b849bc19a0' User entered '04 Dec 2020 11:23:09'	System	04 Dec 2020 16:23:13
	System	04 Dec 2020 16:23:13

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[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 (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-12-10T00:01:41', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '38e318ee-eb0a-411d-9cd6-a213e9159a07' User entered 'No (N)'	System	10 Dec 2020 05:03:10
	System	10 Dec 2020 05:03:10

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

Have you been exposed to someone with 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 (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-12-10T00:01:44', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '38e318ee-eb0a-411d-9cd6-a213e9159a07' User entered 'No (N)'	System	10 Dec 2020 05:03:10
	System	10 Dec 2020 05:03:10

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-12-10T00:01:48', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '38e318ee-eb0a-411d-9cd6-a213e9159a07' User entered '10 Dec 2020 00:01:48'	System	10 Dec 2020 05:03:10
	System	10 Dec 2020 05:03:10

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[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 (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-12-17T00:41:34', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '19e78437-4658-498b-a038-5f5620da733d' User entered 'No (N)'	System	17 Dec 2020 05:41:52
	System	17 Dec 2020 05:41:52

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

Have you been exposed to someone with 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 (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-12-17T00:41:29', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '19e78437-4658-498b-a038-5f5620da733d' User entered 'No (N)'	System	17 Dec 2020 05:41:52
	System	17 Dec 2020 05:41:52

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-12-17T00:41:48', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '19e78437-4658-498b-a038-5f5620da733d' User entered '17 Dec 2020 00:41:48'	System	17 Dec 2020 05:41:52
	System	17 Dec 2020 05:41:52

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[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 (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-12-26T17:16:38', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '9ead4d69-a5fe-402e-a467-934381460151' User entered 'No (N)'	System	26 Dec 2020 22:16:48
	System	26 Dec 2020 22:16:48

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

Have you been exposed to someone with 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 (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-12-26T17:16:42', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '9ead4d69-a5fe-402e-a467-934381460151' User entered 'No (N)'	System	26 Dec 2020 22:16:48
	System	26 Dec 2020 22:16:48

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-12-26T17:16:46', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '9ead4d69-a5fe-402e-a467-934381460151' User entered '26 Dec 2020 17:16:46'	System	26 Dec 2020 22:16:48
	System	26 Dec 2020 22:16:48

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[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 (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-12-31T00:12:19', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '2eec3176-4b64-4884-9ab3-8b6caaa40400' User entered 'No (N)'	System	31 Dec 2020 05:12:28
	System	31 Dec 2020 05:12:28

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

Have you been exposed to someone with 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 (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-12-31T00:12:22', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '2eec3176-4b64-4884-9ab3-8b6caaa40400' User entered 'No (N)'	System	31 Dec 2020 05:12:28
	System	31 Dec 2020 05:12:28

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2020-12-31T00:12:25', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '2eec3176-4b64-4884-9ab3-8b6caaa40400' User entered '31 Dec 2020 00:12:25'	System	31 Dec 2020 05:12:28
	System	31 Dec 2020 05:12:28

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[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 (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2021-01-07T00:01:35', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '7b0d5f74-5ebd-4965-858b-884aa1238ae8' User entered 'No (N)'	System	07 Jan 2021 05:01:57
	System	07 Jan 2021 05:01:57

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

Have you been exposed to someone with 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 (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2021-01-07T00:01:39', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '7b0d5f74-5ebd-4965-858b-884aa1238ae8'	System	07 Jan 2021 05:01:57
User entered 'No (N)'	System	07 Jan 2021 05:01:57

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2021-01-07T00:01:44', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '7b0d5f74-5ebd-4965-858b-884aa1238ae8' User entered '07 Jan 2021 00:01:44'	System	07 Jan 2021 05:01:57
	System	07 Jan 2021 05:01:57

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[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 (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2021-01-15T08:22:27', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '624bc18b-9101-42d5-833e-1d569bb535d4'	System	15 Jan 2021 13:22:38
User entered 'No (N)'	System	15 Jan 2021 13:22:38

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Have you been exposed to someone with 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 (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2021-01-15T08:22:32', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '624bc18b-9101-42d5-833e-1d569bb535d4'	System	15 Jan 2021 13:22:38
User entered 'No (N)'	System	15 Jan 2021 13:22:38

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2021-01-15T08:22:36', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '624bc18b-9101-42d5-833e-1d569bb535d4'	System	15 Jan 2021 13:22:38
User entered '15 Jan 2021 08:22:36'	System	15 Jan 2021 13:22:38

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[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 (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2021-01-21T08:56:39', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'b68feb4b-4b2e-43ae-b2b5-0938a30fa262'	System	21 Jan 2021 13:57:12
User entered 'No (N)'	System	21 Jan 2021 13:57:12

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

Have you been exposed to someone with 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 (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2021-01-21T08:56:41', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'b68feb4b-4b2e-43ae-b2b5-0938a30fa262'	System	21 Jan 2021 13:57:12
User entered 'No (N)'	System	21 Jan 2021 13:57:12

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2021-01-21T08:56:44', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'b68feb4b-4b2e-43ae-b2b5-0938a30fa262' User entered '21 Jan 2021 08:56:44'	System	21 Jan 2021 13:57:12

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[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 (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2021-01-28T00:01:32', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '9e4110fc-d729-4dc1-9eee-e2dc943237e6' User entered 'No (N)'	System	03 Feb 2021 13:53:51
	System	03 Feb 2021 13:53:51

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

Have you been exposed to someone with 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 (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2021-01-28T00:01:34', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '9e4110fc-d729-4dc1-9eee-e2dc943237e6' User entered 'No (N)'	System	03 Feb 2021 13:53:51

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2021-01-28T00:01:37', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '9e4110fc-d729-4dc1-9eee-e2dc943237e6' User entered '28 Jan 2021 00:01:37'	System	03 Feb 2021 13:53:51
	System	03 Feb 2021 13:53:51

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[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 (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2021-02-05T10:26:12', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '4010b4df-49ec-499b-a622-fbc7276ad11b' User entered 'No (N)'	System	08 Feb 2021 16:15:39
	System	08 Feb 2021 16:15:39

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Have you been exposed to someone with 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 (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2021-02-05T10:26:14', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '4010b4df-49ec-499b-a622-fbc7276ad11b' User entered 'No (N)'	System	08 Feb 2021 16:15:39

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2021-02-05T10:26:17', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '4010b4df-49ec-499b-a622-fbc7276ad11b' User entered '05 Feb 2021 10:26:17'	System	08 Feb 2021 16:15:39

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[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 (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2021-02-11T07:55:38', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'ebda9c15-2a70-44fa-89d5-eaaf6dd41050' User entered 'No (N)'	System	11 Feb 2021 12:55:54
	System	11 Feb 2021 12:55:54

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Have you been exposed to someone with 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 (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2021-02-11T07:55:45', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'ebda9c15-2a70-44fa-89d5-eaaf6dd41050' User entered 'No (N)'	System	11 Feb 2021 12:55:54
	System	11 Feb 2021 12:55:54

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2021-02-11T07:55:50', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'ebda9c15-2a70-44fa-89d5-eaaf6dd41050' User entered '11 Feb 2021 07:55:50'	System	11 Feb 2021 12:55:54
	System	11 Feb 2021 12:55:54

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[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 (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2021-02-18T07:50:21', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'd673ef70-6fc7-4948-863e-f390190e1535'	System	18 Feb 2021 12:50:29
User entered 'No (N)'	System	18 Feb 2021 12:50:29

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

Have you been exposed to someone with 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 (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2021-02-18T07:50:23', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'd673ef70-6fc7-4948-863e-f390190e1535'	System	18 Feb 2021 12:50:29
User entered 'No (N)'	System	18 Feb 2021 12:50:29

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2021-02-18T07:50:26', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'd673ef70-6fc7-4948-863e-f390190e1535' User entered '18 Feb 2021 07:50:26'	System	18 Feb 2021 12:50:29
	System	18 Feb 2021 12:50:29

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[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 (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2021-02-25T15:46:46', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '4e2fe8d9-ff61-4659-945d-50234d70686b' User entered 'No (N)'	System	26 Feb 2021 03:57:44
	System	26 Feb 2021 03:57:44

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

Have you been exposed to someone with 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 (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2021-02-25T15:46:48', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '4e2fe8d9-ff61-4659-945d-50234d70686b' User entered 'No (N)'	System	26 Feb 2021 03:57:44

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2021-02-25T15:46:56', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '4e2fe8d9-ff61-4659-945d-50234d70686b' User entered '25 Feb 2021 15:46:56'	System	26 Feb 2021 03:57:44

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[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 (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2021-03-04T00:22:27-05:00', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '66e54261-e0d4-4700-80b7-6985f28ea7fa' User entered 'No (N)'	System	04 Mar 2021 05:22:43
	System	04 Mar 2021 05:22:43

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

Have you been exposed to someone with 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 (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2021-03-04T00:22:34-05:00', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '66e54261-e0d4-4700-80b7-6985f28ea7fa' User entered 'No (N)'	System	04 Mar 2021 05:22:43
	System	04 Mar 2021 05:22:43

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2021-03-04T00:22:37-05:00', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '66e54261-e0d4-4700-80b7-6985f28ea7fa' User entered '04 Mar 2021 05:22:37'	System	04 Mar 2021 05:22:43
	System	04 Mar 2021 05:22:43

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[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 (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2021-03-12T22:51:20-05:00', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'd5f3b1cb-08c0-4794-9e14-de01cb621755'	System	13 Mar 2021 03:55:00
User entered 'No (N)'	System	13 Mar 2021 03:55:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

Have you been exposed to someone with 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 (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2021-03-12T22:51:24-05:00', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'd5f3b1cb-08c0-4794-9e14-de01cb621755'	System	13 Mar 2021 03:55:00
User entered 'No (N)'	System	13 Mar 2021 03:55:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2021-03-12T22:51:27-05:00', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: 'd5f3b1cb-08c0-4794-9e14-de01cb621755'	System	13 Mar 2021 03:55:00
User entered '12 Mar 2021 22:51:27'	System	13 Mar 2021 03:55:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[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 (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2021-03-18T07:10:44-04:00', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '4f0fccfd-9818-4060-a582-562e597d884c'	System	18 Mar 2021 11:10:54
User entered 'No (N)'	System	18 Mar 2021 11:10:54

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Have you been exposed to someone with 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 (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2021-03-18T07:10:48-04:00', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '4f0fccfd-9818-4060-a582-562e597d884c'	System	18 Mar 2021 11:10:54
User entered 'No (N)'	System	18 Mar 2021 11:10:54

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2021-03-18T07:10:52-04:00', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '4f0fccfd-9818-4060-a582-562e597d884c' User entered '18 Mar 2021 07:10:52'	System	18 Mar 2021 11:10:54
	System	18 Mar 2021 11:10:54

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[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 (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2021-03-25T00:50:36-04:00', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '030ad9eb-fb65-4997-aed5-50e349b4c5b9'	System	25 Mar 2021 04:50:50
User entered 'No (N)'	System	25 Mar 2021 04:50:50

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

Have you been exposed to someone with 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 (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2021-03-25T00:50:09-04:00', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '030ad9eb-fb65-4997-aed5-50e349b4c5b9' User entered 'No (N)'	System	25 Mar 2021 04:50:50
	System	25 Mar 2021 04:50:50

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2021-03-25T00:50:46-04:00', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '030ad9eb-fb65-4997-aed5-50e349b4c5b9' User entered '25 Mar 2021 00:50:46'	System	25 Mar 2021 04:50:50
	System	25 Mar 2021 04:50:50

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[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 (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2021-04-01T00:02:34-04:00', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '3c4dc62e-1224-4ee9-9b94-1bcaceb14f37'	System	01 Apr 2021 04:04:44
User entered 'Yes (Y)'	System	01 Apr 2021 04:04:44

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

Have you been exposed to someone with 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 (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2021-04-01T00:02:40-04:00', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '3c4dc62e-1224-4ee9-9b94-1bcaceb14f37'	System	01 Apr 2021 04:04:44
User entered 'No (N)'	System	01 Apr 2021 04:04:44

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[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 (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2021-04-01T00:02:44-04:00', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '3c4dc62e-1224-4ee9-9b94-1bcaceb14f37'	System	01 Apr 2021 04:04:44
User entered 'No (N)'	System	01 Apr 2021 04:04:44

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[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 (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2021-04-01T00:02:51-04:00', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '3c4dc62e-1224-4ee9-9b94-1bcaceb14f37'	System	01 Apr 2021 04:04:44
User entered 'Yes (Y)'	System	01 Apr 2021 04:04:44

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2021-04-01T00:02:57-04:00', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '3c4dc62e-1224-4ee9-9b94-1bcaceb14f37'	System	01 Apr 2021 04:04:44
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	01 Apr 2021 04:04:44

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2021-04-01T00:03:00-04:00', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '3c4dc62e-1224-4ee9-9b94-1bcaceb14f37'	System	01 Apr 2021 04:04:44
User entered '01 Apr 2021 00:03:00'	System	01 Apr 2021 04:04:44

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[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 (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2021-04-08T14:07:18-04:00', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '965222ee-0f83-40c7-bb98-2405f77f2e2e' User entered 'No (N)'	System	08 Apr 2021 18:07:28
	System	08 Apr 2021 18:07:28

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

Have you been exposed to someone with 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 (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2021-04-08T14:07:20-04:00', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '965222ee-0f83-40c7-bb98-2405f77f2e2e' User entered 'No (N)'	System	08 Apr 2021 18:07:28
	System	08 Apr 2021 18:07:28

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2021-04-08T14:07:24-04:00', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '965222ee-0f83-40c7-bb98-2405f77f2e2e' User entered '08 Apr 2021 14:07:24'	System	08 Apr 2021 18:07:28
	System	08 Apr 2021 18:07:28

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[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 (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2021-04-15T19:20:38-04:00', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '7642f649-3a1f-44ae-a002-3f78340783fc' User entered 'No (N)'	System	15 Apr 2021 23:21:12
	System	15 Apr 2021 23:21:12

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

Have you been exposed to someone with 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 (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2021-04-15T19:20:41-04:00', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '7642f649-3a1f-44ae-a002-3f78340783fc' User entered 'No (N)'	System	15 Apr 2021 23:21:12
	System	15 Apr 2021 23:21:12

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2021-04-15T19:20:44-04:00', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '7642f649-3a1f-44ae-a002-3f78340783fc' User entered '15 Apr 2021 19:20:44'	System	15 Apr 2021 23:21:12
	System	15 Apr 2021 23:21:12

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[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 (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2021-04-24T12:50:43-04:00', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '7c0ab497-8362-40a1-b73f-06c3d33a03ea' User entered 'No (N)'	System	24 Apr 2021 16:50:53
	System	24 Apr 2021 16:50:53

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

Have you been exposed to someone with 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 (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2021-04-24T12:50:45-04:00', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '7c0ab497-8362-40a1-b73f-06c3d33a03ea' User entered 'No (N)'	System	24 Apr 2021 16:50:53

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2021-04-24T12:50:48-04:00', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '7c0ab497-8362-40a1-b73f-06c3d33a03ea' User entered '24 Apr 2021 12:50:48'	System	24 Apr 2021 16:50:53
	System	24 Apr 2021 16:50:53

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 12:47:00

US3352015

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:10:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:47:00
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 12:47:00

US3352015

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:10:26

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 13:12:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2021-03-04T00:22:42-05:00', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '34d57de2-dcc9-41ef-901e-4bcc0ea068f0'	System	04 Mar 2021 05:22:48
User entered 'No (N)'	System	04 Mar 2021 05:22:48

US3352015

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:10:26

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:12:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9CD41B6F-B2C9-4EAB-9894-11C173FD6B7D)', Time: '2021-03-04T00:22:44-05:00', User OID: 'PatientReportedOutcome (US3352015)', ODM File OID: '34d57de2-dcc9-41ef-901e-4bcc0ea068f0' User entered '04 Mar 2021 05:22:44'	System	04 Mar 2021 05:22:48
	System	04 Mar 2021 05:22:48

US3352015

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:47
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4)	27 Oct 2020 18:27:12

US3352015

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:47
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '27 Oct 2020'	Yulexis Amestoy (b) (4)	27 Oct 2020 18:27:12

US3352015

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:47
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Contact Made (CONTACT MADE)'	Yulexis Amestoy (b) (4)	27 Oct 2020 18:27:12

US3352015

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:47
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered empty.	Yulexis Amestoy (b) (4)	27 Oct 2020 18:27:12

US3352015

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:47
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4)	27 Oct 2020 18:27:03

US3352015

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:09:47
User entered 'I'	System	27 Oct 2020 18:27:03

US3352015

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:38:48
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4)	30 Nov 2020 17:24:58

US3352015

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:38:48
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '30 Nov 2020'	Yulexis Amestoy (b) (4)	30 Nov 2020 17:24:58

US3352015

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:38:48
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Contact Made (CONTACT MADE)'	Yulexis Amestoy (b) (4)	30 Nov 2020 17:24:58

US3352015

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:38:48
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered empty.	Yulexis Amestoy (b) (4)	30 Nov 2020 17:24:58

US3352015

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:38:52
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4)	30 Nov 2020 17:24:51

US3352015

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:38:52
User entered 'I'	System	30 Nov 2020 17:24:51

US3352015

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:38:37
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Dec 2020 16:19:47

US3352015

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:38:37
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '30 Dec 2020'	(b) (4), (b) (6)	30 Dec 2020 16:19:47

US3352015

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:38:37
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	30 Dec 2020 16:19:47

US3352015

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:38:37
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered empty.	(b) (4), (b) (6)	30 Dec 2020 16:19:47

US3352015

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:38:41
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Dec 2020 16:19:55

US3352015

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:38:41
User entered 'I'	System	30 Dec 2020 16:19:55

US3352015

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:38:24
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Feb 2021 18:00:03

US3352015

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:38:24
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '1 Feb 2021'	(b) (4), (b) (6)	01 Feb 2021 18:00:03

US3352015

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:38:24
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	01 Feb 2021 18:00:03

US3352015

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:38:24
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered empty.	(b) (4), (b) (6)	01 Feb 2021 18:00:03

US3352015

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:38:28
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Feb 2021 18:00:37

US3352015

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:38:28
User entered 'I'	System	01 Feb 2021 18:00:37

US3352015

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:10:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:57
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Mar 2021 19:00:51

US3352015

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:10:26

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:57
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '2 Mar 2021'	(b) (4), (b) (6)	02 Mar 2021 19:00:51

US3352015

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:57
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	02 Mar 2021 19:00:51

US3352015

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:10:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:57
User entered 'VISIT4'	System	02 Mar 2021 19:00:51

US3352015

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:57
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'No (N)'	(b) (4), (b) (6)	30 Mar 2021 19:23:01

US3352015

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:57
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 19:23:01

US3352015

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:57
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 19:23:01

US3352015

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:26

Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:57
User entered empty.	System	30 Mar 2021 19:23:01

US3352015

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:57
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 19:23:01

US3352015

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:57
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 19:23:01

US3352015

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:57
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 19:23:01

US3352015

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:57
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 19:23:01

US3352015

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:57
User entered empty.	System	30 Mar 2021 19:23:01

US3352015

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:57
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 19:23:01

US3352015

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:57
User entered empty.	System	30 Mar 2021 19:23:01

US3352015

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:57
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 19:23:01

US3352015

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:57
User entered empty.	System	30 Mar 2021 19:23:01

US3352015

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:57
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 19:23:01

US3352015

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:57
User entered empty.	System	30 Mar 2021 19:23:01

US3352015

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:26

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:57

US3352015

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:10:26

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:57

US3352015

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:10:26

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:57
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'No (N)'	(b) (4), (b) (6)	02 Mar 2021 19:01:25

US3352015

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:10:26

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:57
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered empty.	(b) (4), (b) (6)	02 Mar 2021 19:01:25

US3352015

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:57
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Mar 2021 19:01:40

US3352015

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:26

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:57
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '2 Mar 2021'	(b) (4), (b) (6)	02 Mar 2021 19:01:40

US3352015

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:26

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:57
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '13:27'	(b) (4), (b) (6)	02 Mar 2021 19:01:40

US3352015

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:26

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:57
User entered '2 Mar 2021 13:27'	System	02 Mar 2021 19:01:40

US3352015

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:57
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Mar 2021 19:01:45

US3352015

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:57
User entered 'I'	System	02 Mar 2021 19:01:45

US3352015

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Mar 2021 14:36:31

US3352015

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '29 Mar 2021'	(b) (4), (b) (6)	29 Mar 2021 14:36:31

US3352015

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	29 Mar 2021 14:36:31

US3352015

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 14:36:31

US3352015

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Mar 2021 14:36:35

US3352015

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:26

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Mar 2021 14:36:35

US3352015

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 May 2021 13:24:35

US3352015

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
User entered '3 May 2021'	(b) (4), (b) (6)	03 May 2021 13:24:35

US3352015

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	03 May 2021 13:24:35

US3352015

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:10:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 May 2021 13:24:35

US3352015

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 May 2021 13:24:39

US3352015

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:10:26

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 May 2021 13:24:39

US3352015

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

Form: Visit Date

Generated On: 09 Jun 2021 17:10:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:57
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	13 Jan 2021 17:41:17

US3352015

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

Form: Visit Date

Generated On: 09 Jun 2021 17:10:26

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:57
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '13 Jan 2021'	Matthew Muniz (b) (4)	13 Jan 2021 17:41:17

US3352015

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

Form: Visit Date

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:57
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Clinic (Clinic)'	Matthew Muniz (b) (4)	13 Jan 2021 17:41:17

US3352015

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

Form: Visit Date

Generated On: 09 Jun 2021 17:10:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:57
User entered 'UNBLND_DECIDE'	System	13 Jan 2021 17:41:17

US3352015

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

Form: Unblinding

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:57
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '13 Jan 2021'	Matthew Muniz (b) (4)	13 Jan 2021 17:41:42

US3352015

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

Form: Unblinding

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:57
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '0'	Sara Gomez (b) (4)	08 Apr 2021 15:12:00
	(b) (4)	
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:16:16

US3352015

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

Form: Unblinding

Generated On: 09 Jun 2021 17:10:26

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:57
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	13 Jan 2021 17:41:42

US3352015

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

Form: Unblinding

Generated On: 09 Jun 2021 17:10:26

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:57
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. ' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 10:26:31
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. ' answered with 'updated' (Site from DM).	Sara Gomez (b) (4)	08 Apr 2021 15:17:51
	(b) (4)	
User entered 'Amendment 6 or later (Amendment 6 or later)'	Sara Gomez (b) (4)	08 Apr 2021 15:12:00
	(b) (4)	
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 13:17:02
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:16:16

US3352015

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

Form: Unblinding

Generated On: 09 Jun 2021 17:10:26

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:57
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '13 Jan 2021'	Matthew Muniz (b) (4)	13 Jan 2021 17:41:42

US3352015

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

Form: Unblinding

Generated On: 09 Jun 2021 17:10:26

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:57
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'mRNA-1273 (mRNA-1273)'	Matthew Muniz (b) (4)	13 Jan 2021 17:41:42

US3352015

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

Form: Unblinding

Generated On: 09 Jun 2021 17:10:26

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:57
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 11:18:02
User entered 'mRNA-1273 (mRNA-1273)'	Matthew Muniz (b) (4)	13 Jan 2021 17:41:42

US3352015

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

Form: Unblinding

Generated On: 09 Jun 2021 17:10:26

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:57
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 11:18:02
User entered 'mRNA-1273 (mRNA-1273)'	Matthew Muniz (b) (4)	13 Jan 2021 17:41:42

US3352015

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

Form: Unblinding

Generated On: 09 Jun 2021 17:10:26

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:57
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'No (N)'	Matthew Muniz (b) (4)	13 Jan 2021 17:41:42

US3352015

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

Form: Unblinding

Generated On: 09 Jun 2021 17:10:26

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:57
User entered empty.	System	13 Jan 2021 17:41:42

US3352015

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

Form: Unblinding

Generated On: 09 Jun 2021 17:10:26

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:57
User entered empty.	System	13 Jan 2021 17:41:42

US3352015

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:57
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	13 Jan 2021 17:41:53

US3352015

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:26

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:57
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '13 Jan 2021'	Matthew Muniz (b) (4)	13 Jan 2021 17:41:53

US3352015

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:26

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:57
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '10:33'	Matthew Muniz (b) (4)	13 Jan 2021 17:41:53

US3352015

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:10:26

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:57
User entered '13 Jan 2021 10:33'	System	13 Jan 2021 17:41:53

US3352015

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:10:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:57
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	13 Jan 2021 17:42:05

US3352015

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:10:26

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:57
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '13 Jan 2021'	Matthew Muniz (b) (4)	13 Jan 2021 17:42:05

US3352015

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:10:26

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:57
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '10:47'	Matthew Muniz (b) (4)	13 Jan 2021 17:42:05

US3352015

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:31:57
User entered '13 Jan 2021 10:47'	System	13 Jan 2021 17:42:05

US3352015

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:10:26

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:51:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Yes (Y)'	Rosaidaliz Carreira (b) (4)	11 Sep 2020 16:52:14

US3352015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:26

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review and update AE term to reflect involves the Left, Right or Bilateral EARS. Please reconcile with the ConMed eCRF so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 06:14:06
User coded data point as SOC: Ear and labyrinth disorders, HLG: Aural disorders NEC, HLT: Ear disorders NEC, PT: Ear pain, LLT: Earache - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Oct 2020 17:44:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Oct 2020 17:44:28
Data point term sent to Coder	System	13 Oct 2020 17:43:20
Query 'Per DM CLR: Please review and update AE term to reflect involves the Left, Right or Bilateral EARS. Please reconcile with the ConMed eCRF so there is an appropriate match. ' answered with 'SUBJECT CONTACTED. DATA HAS BEEN UPDATED.' (Site from DM).	Rosaidaliz Carreira (b) (4) (b) (4)	13 Oct 2020 17:43:16
Coding entries removed.	Rosaidaliz Carreira (b) (4) (b) (4)	13 Oct 2020 17:43:00
User entered 'RIGHT EARACHE' reason for change: Data Entry Error	Rosaidaliz Carreira (b) (4) (b) (4)	13 Oct 2020 17:43:00
User opened query 'Per DM CLR: Please review and update AE term to reflect involves the Left, Right or Bilateral EARS. Please reconcile with the ConMed eCRF so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 01:30:40
User coded data point as SOC: Ear and labyrinth disorders, HLG: Aural disorders NEC, HLT: Ear disorders NEC, PT: Ear pain, LLT: Earache - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 19:13:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 19:13:38
Data point term sent to Coder	System	11 Sep 2020 19:12:58
User entered 'EARACHE'	Rosaidaliz Carreira (b) (4) (b) (4)	11 Sep 2020 19:12:34

US3352015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:26

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	11 Sep 2020 19:12:34

US3352015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:26

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	11 Sep 2020 19:12:34

US3352015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:26

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	11 Sep 2020 19:12:34

US3352015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '04 Sep 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	11 Sep 2020 19:12:34

US3352015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:26

Start time (00:00-23:59)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	14 Sep 2020 10:05:09
Query 'Data is required. Please provide.' answered with 'TIME UNKNOWN' (Site from System).	Rosaidaliz Carreira (b) (4) (b) (4)	11 Sep 2020 19:13:02
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Sep 2020 19:12:34
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	11 Sep 2020 19:12:34

US3352015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:26

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 19:12:34

US3352015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:26

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	11 Sep 2020 19:12:34

US3352015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
User entered '04 Sep 2020'	Rosaidaliz Carreira (b) (4) (b) (4)	11 Sep 2020 19:12:34

US3352015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:26

End time (00:00-23:59)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	14 Sep 2020 10:05:13
Query 'Data is required. Please provide.' answered with 'TIME UNKNOWN' (Site from System).	Rosaidaliz Carreira (b) (4)	11 Sep 2020 19:13:04
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	11 Sep 2020 19:12:34
User entered empty.	System	11 Sep 2020 19:12:34
	Rosaidaliz Carreira (b) (4)	11 Sep 2020 19:12:34
	(b) (4)	

US3352015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:26

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 19:12:34

US3352015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:26

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Rosaidaliz Carreira (b) (4) (b) (4)	11 Sep 2020 19:12:34

US3352015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:26

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	11 Sep 2020 19:12:34

US3352015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:26

Death

Audit	User	Time (GMT)
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	11 Sep 2020 19:12:34

US3352015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:26

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	11 Sep 2020 19:12:34

US3352015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	11 Sep 2020 19:12:34

US3352015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:26

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	11 Sep 2020 19:12:34

US3352015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:26

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	11 Sep 2020 19:12:34

US3352015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:26

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	11 Sep 2020 19:12:34

US3352015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:26

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	11 Sep 2020 19:12:34

US3352015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:26

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	11 Sep 2020 19:12:34

US3352015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	11 Sep 2020 19:12:34

US3352015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:26

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	11 Sep 2020 19:12:34

US3352015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:26

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Rosaidaliz Carreira (b) (4) (b) (4)	11 Sep 2020 19:12:34

US3352015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:26

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Rosaidaliz Carreira (b) (4) (b) (4)	11 Sep 2020 19:12:34

US3352015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:26

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	Rosaidaliz Carreira (b) (4) (b) (4)	11 Sep 2020 19:12:34

US3352015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:26

None

Audit	User	Time (GMT)
User closed query 'None is checked, but Concomitant System Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).		11 Sep 2020 19:13:18
User entered '0' reason for change: Data Entry Error Rosaidaliz Carreira	(b) (4)	11 Sep 2020 19:13:18
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	(b) (4) System	11 Sep 2020 19:12:34
User entered '1'	Rosaidaliz Carreira (b) (4)	11 Sep 2020 19:12:34
	(b) (4)	

US3352015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:26

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered 'I'	Rosaidaliz Carreira (b) (4) (b) (4)	11 Sep 2020 19:12:34

US3352015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:26

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Rosaidaliz Carreira (b) (4) (b) (4)	11 Sep 2020 19:12:34

US3352015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:26

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Rosaidaliz Carreira (b) (4) (b) (4)	11 Sep 2020 19:12:34

US3352015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
User entered empty.	Rosaidaliz Carreira (b) (4)	11 Sep 2020 19:12:34
	(b) (4)	

US3352015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:26

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	11 Sep 2020 19:12:34

US3352015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:26

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	11 Sep 2020 19:12:34

US3352015

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:10:26

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	11 Sep 2020 19:12:34

US3352015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:26

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:02
User entered 'USA-US066-2021-mRNA-1273-P301000009'	System	30 Mar 2021 13:11:56
User entered 'New'	(b) (4), (b) (6)	30 Mar 2021 13:11:56

US3352015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:26

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Hepatobiliary disorders, HLG: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholecystitis acute, LLT: Acute cholecystitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Mar 2021 15:12:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Mar 2021 15:12:58
Data point term sent to Coder	System	29 Mar 2021 15:11:05
User entered 'Acute Cholecystitis'	(b) (4), (b) (6) (b) (4), (b) (6)	29 Mar 2021 15:10:17

US3352015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:26

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Mar 2021 15:10:17

US3352015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:26

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	29 Mar 2021 15:10:17

US3352015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:26

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	29 Mar 2021 15:10:17

US3352015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Per protocol, SAE start date should be when the subject first began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms (abdominal pain started few days before the subject was admitted to hospital). If not updating the start date, please clarify. ' (Site from Safety).	(b) (4), (b) (6)	28 Apr 2021 13:55:36
Query 'PV Query: Per protocol, SAE start date should be when the subject first began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms (abdominal pain started few days before the subject was admitted to hospital). If not updating the start date, please clarify. ' answered with 'Start date has been updated' (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 19:52:06
User entered '21 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Apr 2021 19:51:54
User opened query 'PV Query: Per protocol, SAE start date should be when the subject first began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms (abdominal pain started few days before the subject was admitted to hospital). If not updating the start date, please clarify. ' (Site from Safety).	(b) (4), (b) (6)	24 Apr 2021 04:12:07
User entered '26 Mar 2021'	(b) (4), (b) (6)	29 Mar 2021 15:10:17

US3352015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 15:10:17

US3352015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:26

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 15:10:17

US3352015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:26

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	29 Mar 2021 15:10:17

US3352015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
User entered '28 Mar 2021'	(b) (4), (b) (6)	29 Mar 2021 15:10:17

US3352015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 15:10:17

US3352015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:26

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 15:10:17

US3352015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:26

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 4 (Grade 4)'	(b) (4), (b) (6)	29 Mar 2021 15:10:17

US3352015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:26

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Mar 2021 15:10:17

US3352015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:26

[Death](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	29 Mar 2021 15:10:17

US3352015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:26

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	29 Mar 2021 15:10:17

US3352015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	29 Mar 2021 15:10:17

US3352015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:26

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '26 Mar 2021'	(b) (4), (b) (6)	29 Mar 2021 15:10:17

US3352015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:26

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '28 Mar 2021'	(b) (4), (b) (6)	29 Mar 2021 15:10:17

US3352015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:26

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	29 Mar 2021 15:10:17

US3352015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:26

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 15:10:17

US3352015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	29 Mar 2021 15:10:17

US3352015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	29 Mar 2021 15:10:17

US3352015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:26

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	29 Mar 2021 15:10:17

US3352015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:26

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	29 Mar 2021 15:10:17

US3352015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:26

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	29 Mar 2021 15:10:17

US3352015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:26

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	29 Mar 2021 15:10:17

US3352015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:26

[None](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	29 Mar 2021 15:10:17

US3352015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:26

[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 06:37:05
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'Data has been updated' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 20:26:44
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 13:30:11
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 05:12:09
User entered '1'	(b) (4), (b) (6)	29 Mar 2021 15:10:17

US3352015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:26

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	29 Mar 2021 15:10:17

US3352015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:26

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	29 Mar 2021 15:10:17

US3352015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 15:10:17

US3352015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:26

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: As per the medical record, the subject was diagnosed with leukocytosis, hepatomegaly, hepatic steatosis and umbilical hernia. Kindly report these events as separate SAE/AE.	(b) (4), (b) (6)	30 Apr 2021 14:05:20
' (Site from Safety). Query 'PV Query: As per the medical record, the subject was diagnosed with leukocytosis, hepatomegaly, hepatic steatosis and umbilical hernia. Kindly report these events as separate SAE/AE.	Surisaday Mederos (b) (4)	29 Apr 2021 18:20:10
' answered with 'Updated ' (Site from Safety). User closed query 'PV Query: Please confirm if Hepatobiliary-Pipida scan was performed? If yes, please send the results. If No, then please state so. ' (Site from Safety). Query 'PV Query: Please confirm if Hepatobiliary-Pipida scan was performed? If yes, please send the results. If No, then please state so. ' answered with 'As per subject scan was not done.' (Site from Safety). User opened query 'PV Query: As per the medical record, the subject was diagnosed with leukocytosis, hepatomegaly, hepatic steatosis and umbilical hernia. Kindly report these events as separate SAE/AE.	(b) (4), (b) (6)	28 Apr 2021 13:55:48
	Rosaidaliz Carreira (b) (4)	27 Apr 2021 19:50:23
' (Site from Safety). User opened query 'PV Query: Please confirm if Hepatobiliary-Pipida scan was performed? If yes, please send the results. If No, then please state so. ' (Site from Safety). 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)	24 Apr 2021 04:12:23
	(b) (4), (b) (6)	24 Apr 2021 04:11:56
	(b) (4), (b) (6)	20 Apr 2021 15:32:40

US3352015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:26

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so' (Site from Safety).	(b) (4), (b) (6)	20 Apr 2021 15:32:37
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 sent today via email. ' (Site from Safety).	Surisaday Mederos (b) (4)	19 Apr 2021 19:46:48
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so' answered with 'SARS COV-2 COVID 19' (Site from Safety).	Surisaday Mederos (b) (4)	19 Apr 2021 19:46:10
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.	(b) (4), (b) (6)	12 Apr 2021 13:08:28
' (Site from Safety).		
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.	(b) (4), (b) (6)	09 Apr 2021 20:27:38
' answered with 'Surgery was entered in Con Procedures.' (Site from Safety).		

US3352015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:26

[Narrative](#)

Audit	User	Time (GMT)
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)	06 Apr 2021 13:09:05
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)	06 Apr 2021 13:08:51
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 13:08:44
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	29 Mar 2021 15:12:09
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	29 Mar 2021 15:12:09
User entered 'Subject reported having pain in his upper right quadrant in his abdomen and decided to go to South Miami Hospital on 26Mar2021. He had Acute Cholecystitis and was hospitalized. On 27Mar2021 in the morning he had a Cholecystectomy. Subject was discharged on 28Mar2021.' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Mar 2021 15:12:09
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	29 Mar 2021 15:10:17
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 15:10:17

US3352015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:26

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Mar 2021 15:10:17

US3352015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:26

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Mar 2021 15:10:17

US3352015

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:10:26

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	29 Mar 2021 15:10:17

US3352015

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:26

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\\23.0.	Coder Import (b) (4)	16 Apr 2021 17:32:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Apr 2021 17:32:51
Data point term sent to Coder	System	16 Apr 2021 17:25:24
User entered 'NAUSEA'	Surisaday Mederos (b) (4)	16 Apr 2021 17:25:03
	(b) (4)	

US3352015

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:26

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Surisaday Mederos (b) (4) (b) (4)	16 Apr 2021 17:25:03

US3352015

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:26

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Surisaday Mederos (b) (4) (b) (4)	16 Apr 2021 17:25:03

US3352015

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
User entered 'No (N)'	Surisaday Mederos (b) (4) (b) (4)	16 Apr 2021 17:25:03

US3352015

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:26

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '25 Mar 2021'	Surisaday Mederos (b) (4) (b) (4)	16 Apr 2021 17:25:03

US3352015

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:26

Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Surisaday Mederos (b) (4)	16 Apr 2021 17:25:03
	(b) (4)	

US3352015

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:26

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 17:25:03

US3352015

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:26

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Surisaday Mederos (b) (4) (b) (4)	16 Apr 2021 17:25:03

US3352015

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
User entered '28 Mar 2021'	Surisaday Mederos (b) (4) (b) (4)	16 Apr 2021 17:25:03

US3352015

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:26

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Surisaday Mederos (b) (4)	16 Apr 2021 17:25:03
	(b) (4)	

US3352015

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:26

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 17:25:03

US3352015

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:26

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Surisaday Mederos (b) (4) (b) (4)	16 Apr 2021 17:25:03

US3352015

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:26

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Surisaday Mederos (b) (4) (b) (4)	16 Apr 2021 17:25:03

US3352015

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:26

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Surisaday Mederos (b) (4) (b) (4)	16 Apr 2021 17:25:03

US3352015

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:26

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Surisaday Mederos (b) (4) (b) (4)	16 Apr 2021 17:25:03

US3352015

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Surisaday Mederos (b) (4) (b) (4)	16 Apr 2021 17:25:03

US3352015

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:26

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Surisaday Mederos (b) (4) (b) (4)	16 Apr 2021 17:25:03

US3352015

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:26

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Surisaday Mederos (b) (4) (b) (4)	16 Apr 2021 17:25:03

US3352015

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:26

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Surisaday Mederos (b) (4) (b) (4)	16 Apr 2021 17:25:03

US3352015

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:26

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Surisaday Mederos (b) (4)	16 Apr 2021 17:25:03
	(b) (4)	

US3352015

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:26

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User entered '0'	Surisaday Mederos (b) (4) (b) (4)	16 Apr 2021 17:25:03

US3352015

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Surisaday Mederos (b) (4) (b) (4)	16 Apr 2021 17:25:03

US3352015

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:26

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Surisaday Mederos (b) (4) (b) (4)	16 Apr 2021 17:25:03

US3352015

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:26

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Surisaday Mederos (b) (4) (b) (4)	16 Apr 2021 17:25:03

US3352015

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:26

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Surisaday Mederos (b) (4) (b) (4)	16 Apr 2021 17:25:03

US3352015

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:26

Action taken with investigational product

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Surisaday Mederos (b) (4)	16 Apr 2021 17:25:03
	(b) (4)	

US3352015

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:26

[None](#)

Audit	User	Time (GMT)
User entered '0'	Surisaday Mederos (b) (4) (b) (4)	16 Apr 2021 17:25:03

US3352015

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:26

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered 'I'	Surisaday Mederos (b) (4) (b) (4)	16 Apr 2021 17:25:03

US3352015

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:26

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Surisaday Mederos (b) (4) (b) (4)	16 Apr 2021 17:25:03

US3352015

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:26

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Surisaday Mederos (b) (4) (b) (4)	16 Apr 2021 17:25:03

US3352015

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
User entered empty.	Surisaday Mederos (b) (4) (b) (4)	16 Apr 2021 17:25:03

US3352015

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:26

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Surisaday Mederos (b) (4) (b) (4)	16 Apr 2021 17:25:03

US3352015

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:26

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	16 Apr 2021 17:25:03

US3352015

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:10:26

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Apr 2021 17:25:03

US3352015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:26

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Hepatobiliary disorders, HLGT: Hepatic and hepatobiliary disorders, HLT: Hepatobiliary signs and symptoms, PT: Hepatomegaly, LLT: Hepatomegaly - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Apr 2021 20:34:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Apr 2021 20:34:05
Data point term sent to Coder	System	29 Apr 2021 16:28:42
User entered 'Hepatomegaly'	Surisaday Mederos (b) (4) (b) (4)	29 Apr 2021 16:28:34

US3352015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:26

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Surisaday Mederos (b) (4)	29 Apr 2021 16:28:34
	(b) (4)	

US3352015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:26

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Surisaday Mederos (b) (4) (b) (4)	29 Apr 2021 16:28:34

US3352015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
User entered 'No (N)'	Surisaday Mederos (b) (4) (b) (4)	29 Apr 2021 16:28:34

US3352015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:26

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '26 Apr 2021'	Surisaday Mederos (b) (4)	29 Apr 2021 16:28:34
	(b) (4)	

US3352015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:26

Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Surisaday Mederos (b) (4)	29 Apr 2021 16:28:34
	(b) (4)	

US3352015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:26

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 16:28:34

US3352015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:26

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Surisaday Mederos (b) (4) (b) (4)	29 Apr 2021 16:28:34

US3352015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
User entered empty.	Surisaday Mederos (b) (4)	29 Apr 2021 16:28:34
	(b) (4)	

US3352015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:26

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Surisaday Mederos (b) (4)	29 Apr 2021 16:28:34
	(b) (4)	

US3352015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:26

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 16:28:34

US3352015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:26

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Surisaday Mederos (b) (4) (b) (4)	29 Apr 2021 16:28:34

US3352015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:26

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Surisaday Mederos (b) (4)	29 Apr 2021 16:28:34
	(b) (4)	

US3352015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:26

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Surisaday Mederos (b) (4)	29 Apr 2021 16:28:34
	(b) (4)	

US3352015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:26

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Surisaday Mederos (b) (4)	29 Apr 2021 16:28:34
	(b) (4)	

US3352015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Surisaday Mederos (b) (4) (b) (4)	29 Apr 2021 16:28:34

US3352015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:26

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Surisaday Mederos (b) (4)	29 Apr 2021 16:28:34
	(b) (4)	

US3352015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:26

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Surisaday Mederos (b) (4)	29 Apr 2021 16:28:34
	(b) (4)	

US3352015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:26

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Surisaday Mederos (b) (4)	29 Apr 2021 16:28:34
	(b) (4)	

US3352015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:26

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Surisaday Mederos (b) (4)	29 Apr 2021 16:28:34
	(b) (4)	

US3352015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:26

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User entered '0'	Surisaday Mederos (b) (4) (b) (4)	29 Apr 2021 16:28:34

US3352015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Surisaday Mederos (b) (4)	29 Apr 2021 16:28:34
	(b) (4)	

US3352015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:26

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Surisaday Mederos (b) (4) (b) (4)	29 Apr 2021 16:28:34

US3352015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:26

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Surisaday Mederos (b) (4) (b) (4)	29 Apr 2021 16:28:34

US3352015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:26

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Surisaday Mederos (b) (4)	29 Apr 2021 16:28:34
	(b) (4)	

US3352015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:26

Action taken with investigational product

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Surisaday Mederos (b) (4)	29 Apr 2021 16:28:34
	(b) (4)	

US3352015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:26

None

Audit	User	Time (GMT)
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	29 Apr 2021 16:28:43
User entered '1' reason for change: Data Entry Error	Surisaday Mederos (b) (4)	29 Apr 2021 16:28:43
	(b) (4)	
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	29 Apr 2021 16:28:34
User entered '0'	Surisaday Mederos (b) (4)	29 Apr 2021 16:28:34
	(b) (4)	

US3352015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:26

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Surisaday Mederos (b) (4) (b) (4)	29 Apr 2021 16:28:34

US3352015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:26

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Surisaday Mederos (b) (4) (b) (4)	29 Apr 2021 16:28:34

US3352015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:26

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Surisaday Mederos (b) (4) (b) (4)	29 Apr 2021 16:28:34

US3352015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
User entered empty.	Surisaday Mederos (b) (4)	29 Apr 2021 16:28:34
	(b) (4)	

US3352015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:26

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Surisaday Mederos (b) (4)	29 Apr 2021 16:28:34
	(b) (4)	

US3352015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:26

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	29 Apr 2021 16:28:34

US3352015

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:10:26

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Apr 2021 16:28:34

US3352015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:26

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: White blood cell disorders, HLT: Leukocytoses NEC, PT: Leukocytosis, LLT: Leukocytosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Apr 2021 20:37:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Apr 2021 20:37:12
Data point term sent to Coder	System	29 Apr 2021 16:30:44
User entered 'Leukocytosis'	Surisaday Mederos (b) (4) (b) (4)	29 Apr 2021 16:30:24

US3352015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:26

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Surisaday Mederos (b) (4) (b) (4)	29 Apr 2021 16:30:24

US3352015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:26

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Surisaday Mederos (b) (4) (b) (4)	29 Apr 2021 16:30:24

US3352015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
User entered 'No (N)'	Surisaday Mederos (b) (4) (b) (4)	29 Apr 2021 16:30:24

US3352015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '26 Mar 2021' reason for change: Data Entry Error	Surisaday Mederos (b) (4)	29 Apr 2021 16:30:49
User entered '26 Apr 2021'	Surisaday Mederos (b) (4)	29 Apr 2021 16:30:24

US3352015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:26

Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Surisaday Mederos (b) (4)	29 Apr 2021 16:30:24
	(b) (4)	

US3352015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:26

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 16:30:24

US3352015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:26

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Surisaday Mederos (b) (4)	29 Apr 2021 16:30:24
	(b) (4)	

US3352015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:26

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	29 Apr 2021 16:31:16
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	29 Apr 2021 16:31:16
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	29 Apr 2021 16:30:56
User closed query 'End date is prior to Start date. Please correct.' (Site from System).	System	29 Apr 2021 16:30:49
User opened query 'End date is prior to Start date. Please correct.' (Site from System).	System	29 Apr 2021 16:30:24
User entered '27 Mar 2021'	Surisaday Mederos (b) (4) (b) (4)	(b) (4) 29 Apr 2021 16:30:24

US3352015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:26

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Surisaday Mederos (b) (4)	29 Apr 2021 16:30:24
	(b) (4)	

US3352015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:26

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 16:30:24

US3352015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:26

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Surisaday Mederos (b) (4) (b) (4)	29 Apr 2021 16:30:24

US3352015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:26

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Surisaday Mederos (b) (4)	29 Apr 2021 16:30:24
	(b) (4)	

US3352015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:26

Death

Audit	User	Time (GMT)
User entered '0'	Surisaday Mederos (b) (4)	29 Apr 2021 16:30:24
	(b) (4)	

US3352015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:26

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Surisaday Mederos (b) (4)	29 Apr 2021 16:30:24
	(b) (4)	

US3352015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Surisaday Mederos (b) (4) (b) (4)	29 Apr 2021 16:30:24

US3352015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:26

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Surisaday Mederos (b) (4)	29 Apr 2021 16:30:24
	(b) (4)	

US3352015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:26

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Surisaday Mederos (b) (4)	29 Apr 2021 16:30:24
	(b) (4)	

US3352015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:26

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Surisaday Mederos (b) (4)	29 Apr 2021 16:30:24
	(b) (4)	

US3352015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:26

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Surisaday Mederos (b) (4)	29 Apr 2021 16:30:24
	(b) (4)	

US3352015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:26

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User entered '0'	Surisaday Mederos (b) (4)	29 Apr 2021 16:30:24
	(b) (4)	

US3352015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Surisaday Mederos (b) (4)	29 Apr 2021 16:30:24
	(b) (4)	

US3352015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:26

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Surisaday Mederos (b) (4) (b) (4)	29 Apr 2021 16:30:24

US3352015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:26

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Surisaday Mederos (b) (4) (b) (4)	29 Apr 2021 16:30:24

US3352015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:26

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Surisaday Mederos (b) (4) (b) (4)	29 Apr 2021 16:30:24

US3352015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:26

Action taken with investigational product

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Surisaday Mederos (b) (4)	29 Apr 2021 16:30:24
	(b) (4)	

US3352015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:26

None

Audit	User	Time (GMT)
User entered 'I'	Surisaday Mederos (b) (4)	29 Apr 2021 16:30:24
	(b) (4)	

US3352015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:26

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Surisaday Mederos (b) (4)	29 Apr 2021 16:30:24
	(b) (4)	

US3352015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:26

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Surisaday Mederos (b) (4)	29 Apr 2021 16:30:24
	(b) (4)	

US3352015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:26

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Surisaday Mederos (b) (4)	29 Apr 2021 16:31:16
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Apr 2021 16:30:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Apr 2021 16:30:56
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Surisaday Mederos (b) (4)	29 Apr 2021 16:30:56
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Apr 2021 16:30:24
User entered empty.	Surisaday Mederos (b) (4)	29 Apr 2021 16:30:24

US3352015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
User entered empty.	Surisaday Mederos (b) (4)	29 Apr 2021 16:30:24
	(b) (4)	

US3352015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:26

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Surisaday Mederos (b) (4)	29 Apr 2021 16:30:24
	(b) (4)	

US3352015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:26

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	29 Apr 2021 16:30:24

US3352015

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:10:26

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	29 Apr 2021 16:30:24

US3352015

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:10:26

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Hepatobiliary disorders, HLGT: Hepatic and hepatobiliary disorders, HLT: Hepatocellular damage and hepatitis NEC, PT: Hepatic steatosis, LLT: Hepatic steatosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Apr 2021 20:45:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Apr 2021 20:45:13
Data point term sent to Coder	System	29 Apr 2021 16:34:46
User entered 'Hepatic Steatosis'	Surisaday Mederos (b) (4) (b) (4)	29 Apr 2021 16:34:46

US3352015

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:10:26

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Surisaday Mederos (b) (4) (b) (4)	29 Apr 2021 16:34:46

US3352015

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:10:26

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Surisaday Mederos (b) (4) (b) (4)	29 Apr 2021 16:34:46

US3352015

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:10:26

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Surisaday Mederos (b) (4) (b) (4)	29 Apr 2021 16:34:46

US3352015

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:10:26

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '26 Mar 2021'	Surisaday Mederos (b) (4) (b) (4)	29 Apr 2021 16:34:46

US3352015

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:10:26

Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Surisaday Mederos (b) (4)	29 Apr 2021 16:34:46
	(b) (4)	

US3352015

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:10:26

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 16:34:46

US3352015

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:10:26

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Surisaday Mederos (b) (4)	29 Apr 2021 16:34:46
	(b) (4)	

US3352015

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
User entered empty.	Surisaday Mederos (b) (4)	29 Apr 2021 16:34:46
	(b) (4)	

US3352015

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:10:26

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Surisaday Mederos (b) (4)	29 Apr 2021 16:34:46
	(b) (4)	

US3352015

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:10:26

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 16:34:46

US3352015

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:10:26

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Surisaday Mederos (b) (4) (b) (4)	29 Apr 2021 16:34:46

US3352015

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:10:26

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Surisaday Mederos (b) (4) (b) (4)	29 Apr 2021 16:34:46

US3352015

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:10:26

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Surisaday Mederos (b) (4) (b) (4)	29 Apr 2021 16:34:46

US3352015

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:10:26

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Surisaday Mederos (b) (4) (b) (4)	29 Apr 2021 16:34:46

US3352015

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:10:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Surisaday Mederos (b) (4) (b) (4)	29 Apr 2021 16:34:46

US3352015

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:10:26

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Surisaday Mederos (b) (4)	29 Apr 2021 16:34:46
	(b) (4)	

US3352015

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:10:26

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Surisaday Mederos (b) (4)	29 Apr 2021 16:34:46
	(b) (4)	

US3352015

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:10:26

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Surisaday Mederos (b) (4)	29 Apr 2021 16:34:46
	(b) (4)	

US3352015

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:10:26

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Surisaday Mederos (b) (4)	29 Apr 2021 16:34:46
	(b) (4)	

US3352015

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:10:26

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User entered '0'	Surisaday Mederos (b) (4) (b) (4)	29 Apr 2021 16:34:46

US3352015

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:10:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Surisaday Mederos (b) (4)	29 Apr 2021 16:34:46
	(b) (4)	

US3352015

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:10:26

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Surisaday Mederos (b) (4) (b) (4)	29 Apr 2021 16:34:46

US3352015

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:10:26

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Surisaday Mederos (b) (4) (b) (4)	29 Apr 2021 16:34:46

US3352015

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:10:26

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Surisaday Mederos (b) (4) (b) (4)	29 Apr 2021 16:34:46

US3352015

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:10:26

Action taken with investigational product

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Surisaday Mederos (b) (4)	29 Apr 2021 16:34:46
	(b) (4)	

US3352015

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:10:26

None

Audit	User	Time (GMT)
User entered 'I'	Surisaday Mederos (b) (4)	29 Apr 2021 16:34:46
	(b) (4)	

US3352015

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:10:26

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Surisaday Mederos (b) (4)	29 Apr 2021 16:34:46
	(b) (4)	

US3352015

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:10:26

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Surisaday Mederos (b) (4) (b) (4)	29 Apr 2021 16:34:46

US3352015

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:10:26

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Surisaday Mederos (b) (4) (b) (4)	29 Apr 2021 16:34:46

US3352015

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
User entered empty.	Surisaday Mederos (b) (4)	29 Apr 2021 16:34:46
	(b) (4)	

US3352015

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:10:26

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Surisaday Mederos (b) (4)	29 Apr 2021 16:34:46
	(b) (4)	

US3352015

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:10:26

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	29 Apr 2021 16:34:46

US3352015

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:10:26

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	29 Apr 2021 16:34:46

US3352015

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:10:26

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Umbilical hernias, PT: Umbilical hernia, LLT: Umbilical hernia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Apr 2021 20:54:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Apr 2021 20:54:03
Data point term sent to Coder	System	29 Apr 2021 16:38:50
User entered 'Umbilical Hernia'	Surisaday Mederos (b) (4) (b) (4)	29 Apr 2021 16:38:44

US3352015

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:10:26

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Surisaday Mederos (b) (4) (b) (4)	29 Apr 2021 16:38:44

US3352015

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:10:26

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Surisaday Mederos (b) (4) (b) (4)	29 Apr 2021 16:38:44

US3352015

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
User entered 'No (N)'	Surisaday Mederos (b) (4) (b) (4)	29 Apr 2021 16:38:44

US3352015

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:10:26

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '26 Mar 2021'	Surisaday Mederos (b) (4) (b) (4)	29 Apr 2021 16:38:44

US3352015

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:10:26

Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Surisaday Mederos (b) (4)	29 Apr 2021 16:38:44
	(b) (4)	

US3352015

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:10:26

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 16:38:44

US3352015

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:10:26

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Surisaday Mederos (b) (4)	29 Apr 2021 16:38:44
	(b) (4)	

US3352015

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:10:26

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	29 Apr 2021 16:39:05
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	29 Apr 2021 16:39:05
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	29 Apr 2021 16:39:05
User entered '27 Mar 2021' reason for change: Data Entry Error	Surisaday Mederos (b) (4)	29 Apr 2021 16:39:05
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	29 Apr 2021 16:38:44
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	29 Apr 2021 16:38:44
User entered empty.	Surisaday Mederos (b) (4)	29 Apr 2021 16:38:44

US3352015

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:10:26

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Surisaday Mederos (b) (4)	29 Apr 2021 16:38:44
	(b) (4)	

US3352015

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:10:26

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 16:38:44

US3352015

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:10:26

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Surisaday Mederos (b) (4) (b) (4)	29 Apr 2021 16:38:44

US3352015

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:10:26

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Surisaday Mederos (b) (4)	29 Apr 2021 16:38:44
	(b) (4)	

US3352015

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:10:26

Death

Audit	User	Time (GMT)
User entered '0'	Surisaday Mederos (b) (4)	29 Apr 2021 16:38:44
	(b) (4)	

US3352015

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:10:26

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Surisaday Mederos (b) (4)	29 Apr 2021 16:38:44
	(b) (4)	

US3352015

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:10:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Surisaday Mederos (b) (4)	29 Apr 2021 16:38:44
	(b) (4)	

US3352015

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:10:26

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Surisaday Mederos (b) (4)	29 Apr 2021 16:38:44
	(b) (4)	

US3352015

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:10:26

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Surisaday Mederos (b) (4)	29 Apr 2021 16:38:44
	(b) (4)	

US3352015

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:10:26

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Surisaday Mederos (b) (4)	29 Apr 2021 16:38:44
	(b) (4)	

US3352015

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:10:26

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Surisaday Mederos (b) (4)	29 Apr 2021 16:38:44
	(b) (4)	

US3352015

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:10:26

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User entered '0'	Surisaday Mederos (b) (4) (b) (4)	29 Apr 2021 16:38:44

US3352015

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:10:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Surisaday Mederos (b) (4)	29 Apr 2021 16:38:44
	(b) (4)	

US3352015

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:10:26

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Surisaday Mederos (b) (4) (b) (4)	29 Apr 2021 16:38:44

US3352015

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:10:26

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Surisaday Mederos (b) (4) (b) (4)	29 Apr 2021 16:38:44

US3352015

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:10:26

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Surisaday Mederos (b) (4) (b) (4)	29 Apr 2021 16:38:44

US3352015

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:10:26

Action taken with investigational product

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Surisaday Mederos (b) (4)	29 Apr 2021 16:38:44
	(b) (4)	

US3352015

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:10:26

None

Audit	User	Time (GMT)
User entered 'I'	Surisaday Mederos (b) (4)	29 Apr 2021 16:38:44
	(b) (4)	

US3352015

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:10:26

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Surisaday Mederos (b) (4) (b) (4)	29 Apr 2021 16:38:44

US3352015

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:10:26

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Surisaday Mederos (b) (4) (b) (4)	29 Apr 2021 16:38:44

US3352015

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:10:26

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Surisaday Mederos (b) (4) (b) (4)	29 Apr 2021 16:38:44

US3352015

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
User entered empty.	Surisaday Mederos (b) (4)	29 Apr 2021 16:38:44
	(b) (4)	

US3352015

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:10:26

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Surisaday Mederos (b) (4)	29 Apr 2021 16:38:44
	(b) (4)	

US3352015

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:10:26

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	29 Apr 2021 16:38:44

US3352015

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:10:26

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Apr 2021 16:38:44

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:10:26

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:51:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Aug 2020 16:05:23

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:10:26

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE SODIUM SESQUIHYDRATE, PRODUCTSYNONYM: PROTONIX [PANTOPRAZOLE SODIUM SESQUIHYDRATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Aug 2020 09:57:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Aug 2020 09:57:36
Data point term sent to Coder	System	18 Aug 2020 12:38:24
User closed query 'For coding purposes, references indicate different formulations for PROTONIX. Please provide generic ingredients, complete, accurate trade name and update the term with your response.' (Site from System).	System	18 Aug 2020 12:38:05
Query 'For coding purposes, references indicate different formulations for PROTONIX.	Wanda Delgado (b) (4)	18 Aug 2020 12:38:05
Please provide generic ingredients, complete, accurate trade name and update the term with your response.' answered with 'Data updated ' (Site from System).		
User entered 'PROTONIX (Generic: Pantoprazole)' reason for change: Data Entry Error	Wanda Delgado (b) (4)	18 Aug 2020 12:37:57
User opened query 'For coding purposes, references indicate different formulations for PROTONIX. Please provide generic ingredients, complete, accurate trade name and update the term with your response.' (Site from System).	Coder Import (b) (4)	14 Aug 2020 19:35:16
Data point term sent to Coder	System	06 Aug 2020 16:06:33
User entered 'PROTONIX'	(b) (4), (b) (6)	06 Aug 2020 16:06:15

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:10:26

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 16:06:15

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:10:26

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'HEARTBURN'	(b) (4), (b) (6)	06 Aug 2020 16:06:15

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:10:26

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '40'	(b) (4), (b) (6)	06 Aug 2020 16:06:15

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:10:26

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'mg (mg)'	(b) (4), (b) (6)	06 Aug 2020 16:06:15

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:10:26

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 16:06:15

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:10:26

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'once daily (QD)'	(b) (4), (b) (6)	06 Aug 2020 16:06:15

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:10:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 16:06:15

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:10:26

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	06 Aug 2020 16:06:15

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:10:26

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 16:06:15

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:10:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	10 Aug 2020 17:19:29
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	06 Aug 2020 16:09:38
answered with 'MEDICATION IS ONGOING AND HAS BEEN TAKEN WITHIN LAST 28 DAYS.'		
(Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	06 Aug 2020 16:06:15
User entered '06 Jun 2020'	(b) (4), (b) (6)	06 Aug 2020 16:06:15

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:10:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 16:06:15

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:10:26

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Aug 2020 16:06:15

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:10:26

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 16:06:15

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:10:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 16:06:15

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:10:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 16:06:15

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:10:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 16:06:15

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:10:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Aug 2020 16:06:15

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:10:26

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: SERTRALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Aug 2020 16:12:15
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Aug 2020 16:12:15
Data point term sent to Coder	System	06 Aug 2020 16:11:37
User entered 'SERTRALINE'	(b) (4), (b) (6)	06 Aug 2020 16:11:00

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:10:26

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 16:11:00

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:10:26

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'ANXIETY'	(b) (4), (b) (6)	06 Aug 2020 16:11:00

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:10:26

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '100'	(b) (4), (b) (6)	06 Aug 2020 16:11:00

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:10:26

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'mg (mg)'	(b) (4), (b) (6)	06 Aug 2020 16:11:00

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:10:26

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 16:11:00

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:10:26

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'once daily (QD)'	(b) (4), (b) (6)	06 Aug 2020 16:11:00

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:10:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 16:11:00

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:10:26

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	06 Aug 2020 16:11:00

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:10:26

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 16:11:00

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:10:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	10 Aug 2020 17:19:35
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.' answered with 'MEDICATION IS ONGOING AND HAS BEEN TAKEN WITHIN LAST 28 DAYS.' (Site from System).	(b) (4), (b) (6)	06 Aug 2020 16:11:05
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	06 Aug 2020 16:11:00
User entered '01 Jun 2019'	(b) (4), (b) (6)	06 Aug 2020 16:11:00

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:10:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 16:11:00

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:10:26

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Aug 2020 16:11:00

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:10:26

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 16:11:00

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:10:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 16:11:00

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:10:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 16:11:00

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:10:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 16:11:00

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:10:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Aug 2020 16:11:00

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:10:26

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:35:33
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 16:57:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 16:57:41
Data point term sent to Coder	System	11 Sep 2020 16:57:05
User entered 'TYLENOL'	Rosaidaliz Carreira (b) (4) (b) (4)	11 Sep 2020 16:56:53

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:10:26

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:35:33
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'No (N)'	Rosaidaliz Carreira (b) (4)	11 Sep 2020 16:56:53

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:10:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:35:33
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'EARACHE'	Rosaidaliz Carreira (b) (4)	11 Sep 2020 16:56:53

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:10:26

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:35:33
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '1000'	Rosaidaliz Carreira (b) (4)	11 Sep 2020 16:56:53

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:10:26

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:35:33
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'mg (mg)'	Rosaidaliz Carreira (b) (4)	11 Sep 2020 16:56:53

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:10:26

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:35:33
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered empty.	Rosaidaliz Carreira (b) (4)	11 Sep 2020 16:56:53

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:10:26

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:35:33
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'once (ONCE)'	Rosaidaliz Carreira (b) (4)	11 Sep 2020 16:56:53

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:10:26

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:35:33
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered empty.	Rosaidaliz Carreira (b) (4)	11 Sep 2020 16:56:53

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:10:26

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:35:33
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Oral (ORAL)'	Rosaidaliz Carreira (b) (4)	11 Sep 2020 16:56:53

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:10:26

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:35:33
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered empty.	Rosaidaliz Carreira (b) (4)	11 Sep 2020 16:56:53

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:10:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:35:33
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '04 Sep 2020'	Rosaidaliz Carreira (b) (4)	11 Sep 2020 16:56:53

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:10:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:35:33
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '0'	Rosaidaliz Carreira (b) (4)	11 Sep 2020 16:56:53

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:10:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:35:33
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'No (N)'	Rosaidaliz Carreira (b) (4)	11 Sep 2020 16:56:53

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:35:33
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '04 Sep 2020'	Rosaidaliz Carreira (b) (4)	11 Sep 2020 16:56:53

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:10:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:35:33
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'No (N)'	Rosaidaliz Carreira (b) (4)	11 Sep 2020 16:56:53

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:10:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:35:33
User entered empty.	System	11 Sep 2020 16:56:53

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:10:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:35:33
User entered empty.	System	11 Sep 2020 16:56:53

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:10:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:35:33
User entered empty.	System	11 Sep 2020 16:56:53

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:10:26

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: KETOROLAC TROMETHAMINE, PRODUCTSYNONYM: TORADOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 08:09:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 08:09:34
Data point term sent to Coder	System	16 Apr 2021 17:24:23
Data point term sent to Coder	System	16 Apr 2021 17:18:14
User entered 'TORADOL'	Surisaday Mederos (b) (4) (b) (4)	16 Apr 2021 17:18:11

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:10:26

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'No (N)'	Surisaday Mederos (b) (4)	16 Apr 2021 17:18:11

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:10:26

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'ACUTE CHOLECYSTECTOMY'	Surisaday Mederos (b) (4)	16 Apr 2021 17:23:25
reason for change: Data Entry Error	(b) (4)	
User entered 'CHOLECYSTECTOMY'	Surisaday Mederos (b) (4)	16 Apr 2021 17:18:11
	(b) (4)	

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:10:26

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '15'	Surisaday Mederos (b) (4)	16 Apr 2021 17:18:11

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:10:26

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'mg (mg)'	Surisaday Mederos (b) (4)	16 Apr 2021 17:18:11
	(b) (4)	

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:10:26

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered empty.	Surisaday Mederos (b) (4)	16 Apr 2021 17:18:11
	(b) (4)	

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:10:26

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'once daily (QD)'	Surisaday Mederos (b) (4)	16 Apr 2021 17:18:11
	(b) (4)	

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:10:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered empty.	Surisaday Mederos (b) (4)	16 Apr 2021 17:18:11
	(b) (4)	

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:10:26

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Intravenous (INTRAVENOUS)'	Surisaday Mederos (b) (4)	16 Apr 2021 17:18:11

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:10:26

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered empty.	Surisaday Mederos (b) (4)	16 Apr 2021 17:18:11
	(b) (4)	

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '26 Mar 2021'	Surisaday Mederos (b) (4)	16 Apr 2021 17:18:11

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:10:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '0'	Surisaday Mederos (b) (4)	16 Apr 2021 17:18:11

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:10:26

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'No (N)'	Surisaday Mederos (b) (4)	16 Apr 2021 17:18:11

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:10:26

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '28 Mar 2021'	Surisaday Mederos (b) (4)	16 Apr 2021 17:18:11

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:10:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'No (N)'	Surisaday Mederos (b) (4)	16 Apr 2021 17:18:11

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:10:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 17:18:11

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:10:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 17:18:11

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:10:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Apr 2021 17:18:11

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:10:26

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: OXYCODONE HYDROCHLORIDE;PARACETAMOL, PRODUCTSYNONYM: PERCOCET [OXYCODONE HYDROCHLORIDE;PARACETAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Apr 2021 17:32:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Apr 2021 17:32:18
Data point term sent to Coder	System	16 Apr 2021 17:20:18
User entered 'PERCOCET'	Surisaday Mederos (b) (4)	16 Apr 2021 17:19:27

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:10:26

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'No (N)'	Surisaday Mederos (b) (4)	16 Apr 2021 17:19:27
	(b) (4)	

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:10:26

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'ABDOMINAL PAIN'	Surisaday Mederos (b) (4)	16 Apr 2021 17:19:27

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:10:26

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '5/325'	Surisaday Mederos (b) (4)	16 Apr 2021 17:19:27
	(b) (4)	

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:10:26

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'mg (mg)'	Surisaday Mederos (b) (4)	16 Apr 2021 17:19:27
	(b) (4)	

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:10:26

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered empty.	Surisaday Mederos (b) (4)	16 Apr 2021 17:19:27
	(b) (4)	

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:10:26

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'other (OTHER)'	Surisaday Mederos (b) (4)	16 Apr 2021 17:19:27
	(b) (4)	

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:10:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'EVERY 6 HOURS AS NEEDED'	Surisaday Mederos (b) (4) (b) (4)	16 Apr 2021 17:19:27

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:10:26

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Oral (ORAL)'	Surisaday Mederos (b) (4)	16 Apr 2021 17:19:27
	(b) (4)	

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:10:26

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered empty.	Surisaday Mederos (b) (4)	16 Apr 2021 17:19:27
	(b) (4)	

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '26 Mar 2021'	Surisaday Mederos (b) (4)	16 Apr 2021 17:19:27

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:10:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '0'	Surisaday Mederos (b) (4)	16 Apr 2021 17:19:27

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:10:26

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'No (N)'	Surisaday Mederos (b) (4)	16 Apr 2021 17:19:27
	(b) (4)	

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:10:26

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '29 Mar 2021'	Surisaday Mederos (b) (4)	16 Apr 2021 17:19:27
	(b) (4)	

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:10:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'No (N)'	Surisaday Mederos (b) (4)	16 Apr 2021 17:19:27

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:10:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 17:19:27

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:10:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 17:19:27

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:10:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 17:19:27

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:10:26

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Apr 2021 17:32:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Apr 2021 17:32:21
Data point term sent to Coder	System	16 Apr 2021 17:21:21
User entered 'TYLENOL'	Surisaday Mederos (b) (4)	16 Apr 2021 17:21:06

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:10:26

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'No (N)'	Surisaday Mederos (b) (4)	16 Apr 2021 17:21:06

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:10:26

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'ABDOMINAL PAIN'	Surisaday Mederos (b) (4)	16 Apr 2021 17:21:06

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:10:26

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '650'	Surisaday Mederos (b) (4)	16 Apr 2021 17:21:06

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:10:26

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'mg (mg)'	Surisaday Mederos (b) (4)	16 Apr 2021 17:21:06
	(b) (4)	

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:10:26

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered empty.	Surisaday Mederos (b) (4)	16 Apr 2021 17:21:06
	(b) (4)	

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:10:26

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'other (OTHER)'	Surisaday Mederos (b) (4)	16 Apr 2021 17:21:06

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:10:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'EVERY 6 HOURS AS NEEDED'	Surisaday Mederos (b) (4)	16 Apr 2021 17:21:06

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:10:26

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Oral (ORAL)'	Surisaday Mederos (b) (4)	16 Apr 2021 17:21:06

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:10:26

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered empty.	Surisaday Mederos (b) (4)	16 Apr 2021 17:21:06
	(b) (4)	

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '26 Mar 2021'	Surisaday Mederos (b) (4)	16 Apr 2021 17:21:06
	(b) (4)	

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:10:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '0'	Surisaday Mederos (b) (4)	16 Apr 2021 17:21:06

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:10:26

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'No (N)'	Surisaday Mederos (b) (4)	16 Apr 2021 17:21:06

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:10:26

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '28 Mar 2021'	Surisaday Mederos (b) (4)	16 Apr 2021 17:21:06

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:10:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'No (N)'	Surisaday Mederos (b) (4)	16 Apr 2021 17:21:06

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:10:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 17:21:06

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:10:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 17:21:06

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:10:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 17:21:06

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:10:26

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE SODIUM, PRODUCTSYNONYM: COLACE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 10:22:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 10:22:50
Data point term sent to Coder	System	16 Apr 2021 17:22:22
User entered 'COLACE'	Surisaday Mederos (b) (4)	16 Apr 2021 17:22:12

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:10:26

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'No (N)'	Surisaday Mederos (b) (4)	16 Apr 2021 17:22:12
	(b) (4)	

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:10:26

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'ABDOMINAL PAIN'	Surisaday Mederos (b) (4)	16 Apr 2021 17:22:12

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:10:26

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '100'	Surisaday Mederos (b) (4)	16 Apr 2021 17:22:12
	(b) (4)	

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:10:26

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'mg (mg)'	Surisaday Mederos (b) (4)	16 Apr 2021 17:22:12
	(b) (4)	

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:10:26

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered empty.	Surisaday Mederos (b) (4)	16 Apr 2021 17:22:12
	(b) (4)	

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:10:26

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'twice daily (BID)'	Surisaday Mederos (b) (4)	16 Apr 2021 17:22:12
	(b) (4)	

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:10:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered empty.	Surisaday Mederos (b) (4)	16 Apr 2021 17:22:12
	(b) (4)	

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:10:26

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Oral (ORAL)'	Surisaday Mederos (b) (4)	16 Apr 2021 17:22:12
	(b) (4)	

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:10:26

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered empty.	Surisaday Mederos (b) (4)	16 Apr 2021 17:22:12
	(b) (4)	

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:10:26

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

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '26 Mar 2021'	Surisaday Mederos (b) (4)	16 Apr 2021 17:22:12
	(b) (4)	

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:10:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '0'	Surisaday Mederos (b) (4)	16 Apr 2021 17:22:12

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:10:26

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'No (N)'	Surisaday Mederos (b) (4)	16 Apr 2021 17:22:12

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:10:26

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '28 Mar 2021'	Surisaday Mederos (b) (4)	16 Apr 2021 17:22:12
	(b) (4)	

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:10:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'No (N)'	Surisaday Mederos (b) (4)	16 Apr 2021 17:22:12

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:10:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	16 Apr 2021 17:22:12

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:10:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 17:22:12

US3352015

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:10:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Apr 2021 17:22:12

US3352015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:10:26

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:51:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	29 Mar 2021 15:13:54
User entered 'No (N)'	Matthew Muniz (b) (4)	26 Mar 2021 13:45:27

US3352015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:10:26

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '27 Mar 2021'	(b) (4), (b) (6)	29 Mar 2021 15:14:24

US3352015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:10:26

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Cholecystectomy'	(b) (4), (b) (6)	29 Mar 2021 15:14:24

US3352015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:10:26

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	29 Mar 2021 15:14:24

US3352015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:10:26

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 15:14:24

US3352015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:10:26

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:34:32
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '26 Mar 2021'	Surisaday Mederos (b) (4)	16 Apr 2021 17:31:09

US3352015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:10:26

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:34:32
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'RIGHT UPPER QUADRANT ULTRASOUND'	Surisaday Mederos (b) (4)	16 Apr 2021 17:31:09

US3352015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:10:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:34:32
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Adverse Event (AE)'	Surisaday Mederos (b) (4)	16 Apr 2021 17:31:09

US3352015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:10:26

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:34:32
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered empty.	Surisaday Mederos (b) (4)	16 Apr 2021 17:31:09

US3352015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:10:26

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:34:33
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '26 Mar 2021'	Surisaday Mederos (b) (4)	16 Apr 2021 17:31:46

US3352015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:10:26

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:34:33
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'SARS COV 2 (COVID 19)'	Surisaday Mederos (b) (4)	16 Apr 2021 17:31:46

US3352015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:10:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:34:33
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Diagnostic (DIAGNOSTIC)'	Surisaday Mederos (b) (4)	16 Apr 2021 17:31:46

US3352015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:10:26

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:34:33
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered empty.	Surisaday Mederos (b) (4)	16 Apr 2021 17:31:46

US3352015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:10:26

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:34:38
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '26 Mar 2021'	Surisaday Mederos (b) (4)	16 Apr 2021 17:32:03

US3352015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:10:26

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:34:38
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'EKG'	Surisaday Mederos (b) (4)	16 Apr 2021 17:32:03

US3352015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:10:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:34:38
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'Diagnostic (DIAGNOSTIC)'	Surisaday Mederos (b) (4)	16 Apr 2021 17:32:03

US3352015

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:10:26

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:34:38
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered empty.	Surisaday Mederos (b) (4)	16 Apr 2021 17:32:03

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'USA-US066-2021-MRNA-1273-P301000009'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

Serious

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'Yes (Y)'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

Death

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'No (N)'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'No (N)'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'Yes (Y)'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'No (N)'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'No (N)'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'No (N)'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 14:05:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:36:03
Un-reviewed for Safety.	System	28 Apr 2021 13:57:52
Signature has been broken.	System	28 Apr 2021 13:57:52
User entered 'Surisaday'	System	28 Apr 2021 13:57:52
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'Howard'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 14:05:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:36:03
Un-reviewed for Safety.	System	28 Apr 2021 13:57:52
Signature has been broken.	System	28 Apr 2021 13:57:52
User entered 'Mederos'	System	28 Apr 2021 13:57:52
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'schwartz'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 14:05:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:36:03
Un-reviewed for Safety.	System	28 Apr 2021 13:57:52
Signature has been broken.	System	28 Apr 2021 13:57:52
User entered '9299 SW 152 ST'	System	28 Apr 2021 13:57:52
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered '7265 SHeridan Street SUite 210'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 14:05:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:36:03
Un-reviewed for Safety.	System	28 Apr 2021 13:57:52
Signature has been broken.	System	28 Apr 2021 13:57:52
User entered 'Miami'	System	28 Apr 2021 13:57:52
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'Pembroke Pines'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'FL'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

Site Address: Postal Code

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 14:05:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:36:03
Un-reviewed for Safety.	System	28 Apr 2021 13:57:52
Signature has been broken.	System	28 Apr 2021 13:57:52
User entered '33031'	System	28 Apr 2021 13:57:52
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered '33024'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:24:46
User entered 'US'	System	30 Mar 2021 13:13:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	30 Apr 2021 14:06:02
User entered '6'	System	28 Apr 2021 13:57:52
User entered '5'	System	19 Apr 2021 19:30:35
User entered '4'	System	19 Apr 2021 13:29:14
User entered '3'	System	12 Apr 2021 13:08:53
User entered '2'	System	08 Apr 2021 13:25:06
User entered '1'	System	30 Mar 2021 13:13:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'USA-US066-2021-MRNA-1273-P301000009'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

Serious

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'Yes (Y)'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

Death

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'No (N)'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'No (N)'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'Yes (Y)'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'No (N)'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'No (N)'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'No (N)'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 14:05:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:36:03
Un-reviewed for Safety.	System	28 Apr 2021 13:57:52
Signature has been broken.	System	28 Apr 2021 13:57:52
User entered 'Surisaday'	System	28 Apr 2021 13:57:52
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'Howard'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 14:05:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:36:03
Un-reviewed for Safety.	System	28 Apr 2021 13:57:52
Signature has been broken.	System	28 Apr 2021 13:57:52
User entered 'Mederos'	System	28 Apr 2021 13:57:52
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'schwartz'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 14:05:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:36:03
Un-reviewed for Safety.	System	28 Apr 2021 13:57:52
Signature has been broken.	System	28 Apr 2021 13:57:52
User entered '9299 SW 152 ST'	System	28 Apr 2021 13:57:52
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered '7265 SHeridan Street SUite 210'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 14:05:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:36:03
Un-reviewed for Safety.	System	28 Apr 2021 13:57:52
Signature has been broken.	System	28 Apr 2021 13:57:52
User entered 'Miami'	System	28 Apr 2021 13:57:52
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'Pembroke Pines'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'FL'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 14:05:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:36:03
Un-reviewed for Safety.	System	28 Apr 2021 13:57:52
Signature has been broken.	System	28 Apr 2021 13:57:52
User entered '33031'	System	28 Apr 2021 13:57:52
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered '33024'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:24:46
User entered 'US'	System	30 Mar 2021 13:13:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	30 Apr 2021 14:06:02
User entered '6'	System	28 Apr 2021 13:57:52
User entered '5'	System	19 Apr 2021 19:30:35
User entered '4'	System	19 Apr 2021 13:29:14
User entered '3'	System	12 Apr 2021 13:08:53
User entered '2'	System	08 Apr 2021 13:25:06
User entered '1'	System	30 Mar 2021 13:13:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:10:26

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '30/Mar/2021 08:13'	System	30 Mar 2021 13:13:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:10:26

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.

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:24:46
Un-reviewed for Safety.		30 Mar 2021 13:13:56
User entered '1' reason for change: New Information		30 Mar 2021 13:13:56
Reviewed for Safety.		30 Mar 2021 13:13:45
User entered '0'		30 Mar 2021 13:12:20

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'USA-US066-2021-MRNA-1273-P301000009'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

Serious

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'Yes (Y)'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

Death

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'No (N)'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'No (N)'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'Yes (Y)'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'No (N)'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'No (N)'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'No (N)'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 14:05:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:36:03
Un-reviewed for Safety.	System	28 Apr 2021 13:57:52
Signature has been broken.	System	28 Apr 2021 13:57:52
User entered 'Surisaday'	System	28 Apr 2021 13:57:52
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'Howard'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 14:05:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:36:03
Un-reviewed for Safety.	System	28 Apr 2021 13:57:52
Signature has been broken.	System	28 Apr 2021 13:57:52
User entered 'Mederos'	System	28 Apr 2021 13:57:52
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'schwartz'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 14:05:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:36:03
Un-reviewed for Safety.	System	28 Apr 2021 13:57:52
Signature has been broken.	System	28 Apr 2021 13:57:52
User entered '9299 SW 152 ST'	System	28 Apr 2021 13:57:52
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered '7265 SHeridan Street SUite 210'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 14:05:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:36:03
Un-reviewed for Safety.	System	28 Apr 2021 13:57:52
Signature has been broken.	System	28 Apr 2021 13:57:52
User entered 'Miami'	System	28 Apr 2021 13:57:52
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'Pembroke Pines'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'FL'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 14:05:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:36:03
Un-reviewed for Safety.	System	28 Apr 2021 13:57:52
Signature has been broken.	System	28 Apr 2021 13:57:52
User entered '33031'	System	28 Apr 2021 13:57:52
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered '33024'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:24:46
User entered 'US'	System	30 Mar 2021 13:13:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	30 Apr 2021 14:06:02
User entered '6'	System	28 Apr 2021 13:57:52
User entered '5'	System	19 Apr 2021 19:30:35
User entered '4'	System	19 Apr 2021 13:29:14
User entered '3'	System	12 Apr 2021 13:08:53
User entered '2'	System	08 Apr 2021 13:25:06
User entered '1'	System	30 Mar 2021 13:13:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:10:26

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '08/Apr/2021 13:25'	System	08 Apr 2021 13:25:06

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:10:26

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.

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 13:08:39
User entered 'I'	(b) (4), (b) (6)	08 Apr 2021 13:25:06

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'USA-US066-2021-MRNA-1273-P301000009'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

Serious

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'Yes (Y)'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

Death

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'No (N)'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'No (N)'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'Yes (Y)'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'No (N)'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'No (N)'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'No (N)'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 14:05:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:36:03
Un-reviewed for Safety.	System	28 Apr 2021 13:57:52
Signature has been broken.	System	28 Apr 2021 13:57:52
User entered 'Surisaday'	System	28 Apr 2021 13:57:52
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'Howard'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 14:05:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:36:03
Un-reviewed for Safety.	System	28 Apr 2021 13:57:52
Signature has been broken.	System	28 Apr 2021 13:57:52
User entered 'Mederos'	System	28 Apr 2021 13:57:52
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'schwartz'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 14:05:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:36:03
Un-reviewed for Safety.	System	28 Apr 2021 13:57:52
Signature has been broken.	System	28 Apr 2021 13:57:52
User entered '9299 SW 152 ST'	System	28 Apr 2021 13:57:52
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered '7265 SHeridan Street SUite 210'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 14:05:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:36:03
Un-reviewed for Safety.	System	28 Apr 2021 13:57:52
Signature has been broken.	System	28 Apr 2021 13:57:52
User entered 'Miami'	System	28 Apr 2021 13:57:52
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'Pembroke Pines'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'FL'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

Site Address: Postal Code

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 14:05:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:36:03
Un-reviewed for Safety.	System	28 Apr 2021 13:57:52
Signature has been broken.	System	28 Apr 2021 13:57:52
User entered '33031'	System	28 Apr 2021 13:57:52
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered '33024'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:24:46
User entered 'US'	System	30 Mar 2021 13:13:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	30 Apr 2021 14:06:02
User entered '6'	System	28 Apr 2021 13:57:52
User entered '5'	System	19 Apr 2021 19:30:35
User entered '4'	System	19 Apr 2021 13:29:14
User entered '3'	System	12 Apr 2021 13:08:53
User entered '2'	System	08 Apr 2021 13:25:06
User entered '1'	System	30 Mar 2021 13:13:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:10:26

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '12/Apr/2021 13:08'	System	12 Apr 2021 13:08:53

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:10:26

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.

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 13:29:00
User entered 'I'	(b) (4), (b) (6)	12 Apr 2021 13:08:53

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'USA-US066-2021-MRNA-1273-P301000009'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

Serious

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'Yes (Y)'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

Death

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'No (N)'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'No (N)'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'Yes (Y)'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'No (N)'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'No (N)'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'No (N)'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 14:05:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:36:03
Un-reviewed for Safety.	System	28 Apr 2021 13:57:52
Signature has been broken.	System	28 Apr 2021 13:57:52
User entered 'Surisaday'	System	28 Apr 2021 13:57:52
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'Howard'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 14:05:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:36:03
Un-reviewed for Safety.	System	28 Apr 2021 13:57:52
Signature has been broken.	System	28 Apr 2021 13:57:52
User entered 'Mederos'	System	28 Apr 2021 13:57:52
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'schwartz'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 14:05:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:36:03
Un-reviewed for Safety.	System	28 Apr 2021 13:57:52
Signature has been broken.	System	28 Apr 2021 13:57:52
User entered '9299 SW 152 ST'	System	28 Apr 2021 13:57:52
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered '7265 SHeridan Street SUite 210'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 14:05:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:36:03
Un-reviewed for Safety.	System	28 Apr 2021 13:57:52
Signature has been broken.	System	28 Apr 2021 13:57:52
User entered 'Miami'	System	28 Apr 2021 13:57:52
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'Pembroke Pines'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'FL'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 14:05:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:36:03
Un-reviewed for Safety.	System	28 Apr 2021 13:57:52
Signature has been broken.	System	28 Apr 2021 13:57:52
User entered '33031'	System	28 Apr 2021 13:57:52
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered '33024'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:24:46
User entered 'US'	System	30 Mar 2021 13:13:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	30 Apr 2021 14:06:02
User entered '6'	System	28 Apr 2021 13:57:52
User entered '5'	System	19 Apr 2021 19:30:35
User entered '4'	System	19 Apr 2021 13:29:14
User entered '3'	System	12 Apr 2021 13:08:53
User entered '2'	System	08 Apr 2021 13:25:06
User entered '1'	System	30 Mar 2021 13:13:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:10:26

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '19/Apr/2021 13:29'	System	19 Apr 2021 13:29:14

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:10:26

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.

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 19:29:46
User entered 'I'	(b) (4), (b) (6)	19 Apr 2021 13:29:14

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'USA-US066-2021-MRNA-1273-P301000009'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

Serious

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'Yes (Y)'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

Death

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'No (N)'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'No (N)'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'Yes (Y)'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'No (N)'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'No (N)'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'No (N)'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 14:05:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:36:03
Un-reviewed for Safety.	System	28 Apr 2021 13:57:52
Signature has been broken.	System	28 Apr 2021 13:57:52
User entered 'Surisaday'	System	28 Apr 2021 13:57:52
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'Howard'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 14:05:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:36:03
Un-reviewed for Safety.	System	28 Apr 2021 13:57:52
Signature has been broken.	System	28 Apr 2021 13:57:52
User entered 'Mederos'	System	28 Apr 2021 13:57:52
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'schwartz'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 14:05:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:36:03
Un-reviewed for Safety.	System	28 Apr 2021 13:57:52
Signature has been broken.	System	28 Apr 2021 13:57:52
User entered '9299 SW 152 ST'	System	28 Apr 2021 13:57:52
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered '7265 SHeridan Street SUite 210'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 14:05:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:36:03
Un-reviewed for Safety.	System	28 Apr 2021 13:57:52
Signature has been broken.	System	28 Apr 2021 13:57:52
User entered 'Miami'	System	28 Apr 2021 13:57:52
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'Pembroke Pines'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'FL'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

Site Address: Postal Code

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 14:05:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:36:03
Un-reviewed for Safety.	System	28 Apr 2021 13:57:52
Signature has been broken.	System	28 Apr 2021 13:57:52
User entered '33031'	System	28 Apr 2021 13:57:52
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered '33024'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:24:46
User entered 'US'	System	30 Mar 2021 13:13:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	30 Apr 2021 14:06:02
User entered '6'	System	28 Apr 2021 13:57:52
User entered '5'	System	19 Apr 2021 19:30:35
User entered '4'	System	19 Apr 2021 13:29:14
User entered '3'	System	12 Apr 2021 13:08:53
User entered '2'	System	08 Apr 2021 13:25:06
User entered '1'	System	30 Mar 2021 13:13:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:10:26

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered '19/Apr/2021 19:30'	System	19 Apr 2021 19:30:35

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:10:26

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.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	28 Apr 2021 13:57:34
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
User entered 'I'	(b) (4), (b) (6)	19 Apr 2021 19:30:35

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'USA-US066-2021-MRNA-1273-P301000009'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

Serious

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'Yes (Y)'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

Death

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'No (N)'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'No (N)'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'Yes (Y)'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'No (N)'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'No (N)'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'No (N)'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 14:05:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:36:03
Un-reviewed for Safety.	System	28 Apr 2021 13:57:52
Signature has been broken.	System	28 Apr 2021 13:57:52
User entered 'Surisaday'	System	28 Apr 2021 13:57:52
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'Howard'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 14:05:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:36:03
Un-reviewed for Safety.	System	28 Apr 2021 13:57:52
Signature has been broken.	System	28 Apr 2021 13:57:52
User entered 'Mederos'	System	28 Apr 2021 13:57:52
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'schwartz'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 14:05:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:36:03
Un-reviewed for Safety.	System	28 Apr 2021 13:57:52
Signature has been broken.	System	28 Apr 2021 13:57:52
User entered '9299 SW 152 ST'	System	28 Apr 2021 13:57:52
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered '7265 SHeridan Street SUite 210'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 14:05:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:36:03
Un-reviewed for Safety.	System	28 Apr 2021 13:57:52
Signature has been broken.	System	28 Apr 2021 13:57:52
User entered 'Miami'	System	28 Apr 2021 13:57:52
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'Pembroke Pines'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'FL'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 14:05:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:36:03
Un-reviewed for Safety.	System	28 Apr 2021 13:57:52
Signature has been broken.	System	28 Apr 2021 13:57:52
User entered '33031'	System	28 Apr 2021 13:57:52
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered '33024'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:24:46
User entered 'US'	System	30 Mar 2021 13:13:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	30 Apr 2021 14:06:02
User entered '6'	System	28 Apr 2021 13:57:52
User entered '5'	System	19 Apr 2021 19:30:35
User entered '4'	System	19 Apr 2021 13:29:14
User entered '3'	System	12 Apr 2021 13:08:53
User entered '2'	System	08 Apr 2021 13:25:06
User entered '1'	System	30 Mar 2021 13:13:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:10:26

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:36:03
User entered '28/Apr/2021 09:57'	System	28 Apr 2021 13:57:52

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:10:26

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.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 14:05:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:36:03
User entered 'I'	(b) (4), (b) (6)	28 Apr 2021 13:57:52

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'USA-US066-2021-MRNA-1273-P301000009'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

Serious

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'Yes (Y)'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

Death

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'No (N)'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'No (N)'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'Yes (Y)'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'No (N)'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'No (N)'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'No (N)'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 14:05:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:36:03
Un-reviewed for Safety.	System	28 Apr 2021 13:57:52
Signature has been broken.	System	28 Apr 2021 13:57:52
User entered 'Surisaday'	System	28 Apr 2021 13:57:52
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'Howard'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 14:05:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:36:03
Un-reviewed for Safety.	System	28 Apr 2021 13:57:52
Signature has been broken.	System	28 Apr 2021 13:57:52
User entered 'Mederos'	System	28 Apr 2021 13:57:52
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'schwartz'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 14:05:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:36:03
Un-reviewed for Safety.	System	28 Apr 2021 13:57:52
Signature has been broken.	System	28 Apr 2021 13:57:52
User entered '9299 SW 152 ST'	System	28 Apr 2021 13:57:52
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered '7265 SHeridan Street SUite 210'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 14:05:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:36:03
Un-reviewed for Safety.	System	28 Apr 2021 13:57:52
Signature has been broken.	System	28 Apr 2021 13:57:52
User entered 'Miami'	System	28 Apr 2021 13:57:52
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'Pembroke Pines'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered 'FL'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 14:05:30
User signature succeeded.	Howard schwartz (b) (4)	28 Apr 2021 21:36:03
Un-reviewed for Safety.	System	28 Apr 2021 13:57:52
Signature has been broken.	System	28 Apr 2021 13:57:52
User entered '33031'	System	28 Apr 2021 13:57:52
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:12:13
User entered '33024'	System	30 Mar 2021 13:11:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:45:24
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 13:24:46
User entered 'US'	System	30 Mar 2021 13:13:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:10:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	30 Apr 2021 14:06:02
User entered '6'	System	28 Apr 2021 13:57:52
User entered '5'	System	19 Apr 2021 19:30:35
User entered '4'	System	19 Apr 2021 13:29:14
User entered '3'	System	12 Apr 2021 13:08:53
User entered '2'	System	08 Apr 2021 13:25:06
User entered '1'	System	30 Mar 2021 13:13:56

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 17:10:26

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '30/Apr/2021 10:06'	System	30 Apr 2021 14:06:02

US3352015

Folder: SAE USA-US066-2021-MRNA-1273-P301000009

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 17:10:26

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.

Audit	User	Time (GMT)
User entered 'I'	(b) (4), (b) (6)	30 Apr 2021 14:06:02