

US3352033 (Prod: Research Centers of America - ERG)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:09:28

All time stamps listed in this document are displayed in GMT

US3352033

Form: Participant Creation

Data signed: (b) (4) 26 Apr 2021 19:55:01

Generated On: 09 Jun 2021 17:09:28

Participant ID

US3352033

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

US3352033

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 19:57:05

Generated On: 09 Jun 2021 17:09:28

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

Visit date (dd MMM yyyy)	06 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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US3352033

Folder: Screening

Form: Demographics

Data signed: (b) (4) 26 Apr 2021 19:57:04

Generated On: 09 Jun 2021 17:09:28

Date of Birth (MMM yyyy)	(b) (6) 1958
Age	61
Age Units	YEARS
Age (Derived)	61
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

US3352033

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 26 Apr 2021 19:57:04

Generated On: 09 Jun 2021 17:09:28

Date of Informed Consent (<i>dd MMM yyyy</i>)	6 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

US3352033

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 26 Apr 2021 19:57:04

Generated On: 09 Jun 2021 17:09:28

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 26 Apr 2021 19:57:05

Generated On: 09 Jun 2021 17:09:28

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 26 Apr 2021 19:57:05

Generated On: 09 Jun 2021 17:09:28

Condition	MIGRAINES
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 26 Apr 2021 19:57:05

Generated On: 09 Jun 2021 17:09:28

Condition	PRESBYOPIA
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Start Year (derived)	2005
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 26 Apr 2021 19:57:05

Generated On: 09 Jun 2021 17:09:28

Condition	TONSILLITIS (RECURRING)
Start date (dd MMM yyyy)	UN UNK 1963
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1963
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1963
Start Year (derived)	1963
Stop Month and Year (derived)	JAN 1963
Stop Year (derived)	1963

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 26 Apr 2021 19:57:05

Generated On: 09 Jun 2021 17:09:28

Condition	DISCAL HERNIA L5-L6
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2019
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	JAN 2019
Stop Year (derived)	2019

US3352033

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 26 Apr 2021 19:57:05

Generated On: 09 Jun 2021 17:09:28

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

US3352033

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 26 Apr 2021 19:57:05

Generated On: 09 Jun 2021 17:09:28

Condition	TONSILLECTOMY
Start date (dd MMM yyyy)	UN UNK 1963
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1963
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1963
Start Year (derived)	1963
Stop Month and Year (derived)	JAN 1963
Stop Year (derived)	1963

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 26 Apr 2021 19:57:05

Generated On: 09 Jun 2021 17:09:28

Condition	ARTHRODESIS L5-L6
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2019
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	JAN 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 26 Apr 2021 19:57:05

Generated On: 09 Jun 2021 17:09:28

Condition	NECK PAIN
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Start Year (derived)	2014
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 26 Apr 2021 19:57:05

Generated On: 09 Jun 2021 17:09:28

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	01 JUL 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JUL 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

US3352033

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 26 Apr 2021 19:57:05

Generated On: 09 Jun 2021 17:09:28

Condition	HYPERTENSION
Start date (dd MMM yyyy)	01 JUL 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JUL 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 19:57:05

Generated On: 09 Jun 2021 17:09:28

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	6 AUG 2020
Time of assessment (00:00-23:59)	11:36 (24 HR)
Vital Signs Date and Time (derived)	6 AUG 2020 11:36
Height (xxx.x)	178.7 cm
Weight (xxx.x)	99.8 kg
BMI (xxx.x)	31.25226 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 19:57:05

Generated On: 09 Jun 2021 17:09:28

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

6 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 19:57:05

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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 19:57:05

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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 19:57:05

Generated On: 09 Jun 2021 17:09:28

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

Visit date (dd MMM yyyy)	6 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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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 26 Apr 2021 19:57:05

Generated On: 09 Jun 2021 17:09:28

What was the date of randomization? (dd MMM yyyy) 06 AUG 2020

What was the participant's randomization number? 101596

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 19:57:05

Generated On: 09 Jun 2021 17:09:28

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 19:57:05

Generated On: 09 Jun 2021 17:09:28

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)	6 AUG 2020
Time of assessment (00:00-23:59)	11:36 (24 HR)
Vital Signs Date and Time (derived)	6 AUG 2020 11:36
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)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	158 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Apr 2021 19:57:05

Generated On: 09 Jun 2021 17:09:28

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)	6 AUG 2020
Time of assessment (00:00-23:59)	13:50 (24 HR)
Vital Signs Date and Time (derived)	6 AUG 2020 13:50
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)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	152 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3352033

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 19:57:05

Generated On: 09 Jun 2021 17:09:28

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.

US3352033

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 26 Apr 2021 19:57:05

Generated On: 09 Jun 2021 17:09:28

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) 6 AUG 2020

What was the treatment time? (00:00-23:59) 13:20 (24 HR)

Treatment Date and Time (derived) 6 AUG 2020 13:20

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 19:57:05

Generated On: 09 Jun 2021 17:09:28

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	6 AUG 2020
Collection time (00:00-23:59)	12:39 (24 HR)
Collection date and time (derived)	6 AUG 2020 12:39

US3352033

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 26 Apr 2021 19:57:05

Generated On: 09 Jun 2021 17:09:28

Collection date (dd MMM yyyy)			6 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:04	6 AUG 2020 12:04
Nasopharyngeal Swab 2	No		

US3352033

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 19:57:05

Generated On: 09 Jun 2021 17:09:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:09:28

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

97.0 °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 14:06

PC Open Date & Time

06 AUG 2020 13:40

PC Close Date & Time

06 AUG 2020 16:10

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:09:28

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	06 AUG 2020 20:27
PC Open Date & Time	06 AUG 2020 17:05
PC Close Date & Time	07 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:09:28

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

98.1 °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

07 AUG 2020 12:00

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3352033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:09:28

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

98.2 °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

08 AUG 2020 18:44

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3352033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:09:28

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

10 AUG 2020 10:09

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3352033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3352033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:09:28

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

98.6 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

11 AUG 2020 18:31

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3352033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:09:28

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

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 AUG 2020 12:01

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3352033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:09:28

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

06 AUG 2020 14:07

PC Open Date & Time

06 AUG 2020 13:40

PC Close Date & Time

06 AUG 2020 16:10

US3352033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:09:28

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

06 AUG 2020 20:28

PC Open Date & Time

06 AUG 2020 17:05

PC Close Date & Time

07 AUG 2020 11:59

US3352033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:09:28

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

07 AUG 2020 12:01

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3352033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 AUG 2020 18:45

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3352033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:09:28

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

10 AUG 2020 10:10

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3352033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:09:28

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3352033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:09:28

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

11 AUG 2020 18:31

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3352033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:09:28

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

12 AUG 2020 12:02

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:09:28

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 ☐

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:09:28

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

No ☒

Yes ☐

PC Time stamp	06 AUG 2020 14:07
PC Open Date & Time	06 AUG 2020 13:40
PC Close Date & Time	06 AUG 2020 16:10

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:09:28

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 ☐

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:09:28

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

No ☒

Yes ☐

PC Time stamp	06 AUG 2020 20:28
PC Open Date & Time	06 AUG 2020 17:05
PC Close Date & Time	07 AUG 2020 11:59

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:09:28

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 ☒

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:09:28

Yes <input type="checkbox"/>	
PC Time stamp	07 AUG 2020 12:01
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:09:28

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 ☒

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:09:28

Yes <input type="checkbox"/>	
PC Time stamp	08 AUG 2020 18:45
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:09:28

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 ☒

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:09:28

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

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:09:28

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 17:09:28

Yes ☐

PC Time stamp

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:09:28

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 ☒

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:09:28

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

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:09:28

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 ☒

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:09:28

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

US3352033

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 19:57:04

Generated On: 09 Jun 2021 17:09:28

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3352033

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 19:57:04

Generated On: 09 Jun 2021 17:09:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352033

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 19:57:04

Generated On: 09 Jun 2021 17:09:28

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 21 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3352033

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 19:57:04

Generated On: 09 Jun 2021 17:09:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352033

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 19:57:04

Generated On: 09 Jun 2021 17:09:28

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 27 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3352033

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 19:57:04

Generated On: 09 Jun 2021 17:09:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352033

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 19:57:05

Generated On: 09 Jun 2021 17:09:28

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 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

US3352033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Apr 2021 19:57:05

Generated On: 09 Jun 2021 17:09:28

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)	10 SEP 2020
Time of assessment (00:00-23:59)	15:35 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 15:35
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)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3352033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Apr 2021 19:57:05

Generated On: 09 Jun 2021 17:09:28

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)	10 SEP 2020
Time of assessment (00:00-23:59)	17:03 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 17:03
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG

US3352033

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 19:57:05

Generated On: 09 Jun 2021 17:09:28

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.

US3352033

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 26 Apr 2021 19:57:05

Generated On: 09 Jun 2021 17:09:28

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) 10 SEP 2020

What was the treatment time? (00:00-23:59) 16:33 (24 HR)

Treatment Date and Time (derived) 10 SEP 2020 16:33

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

US3352033

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 19:57:05

Generated On: 09 Jun 2021 17:09:28

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	10 SEP 2020
Collection time (00:00-23:59)	16:03 (24 HR)
Collection date and time (derived)	10 SEP 2020 16:03

US3352033

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 26 Apr 2021 19:57:05

Generated On: 09 Jun 2021 17:09:28

Collection date (dd MMM yyyy)			10 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:50	10 SEP 2020 15:50
Nasopharyngeal Swab 2	No		

US3352033

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 19:57:05

Generated On: 09 Jun 2021 17:09:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 17:07

PC Open Date & Time

10 SEP 2020 16:53

PC Close Date & Time

10 SEP 2020 19:23

US3352033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:09:28

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 98.4 °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	10 SEP 2020 23:16
PC Open Date & Time	10 SEP 2020 20:18
PC Close Date & Time	11 SEP 2020 11:59

US3352033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:09:28

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

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 04:16

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3352033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:09:28

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

98.4 °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

13 SEP 2020 06:14

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3352033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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

13 SEP 2020 12:48

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3352033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3352033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:09:28

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

98.2 °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

15 SEP 2020 12:01

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3352033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:09:28

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

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 12:34

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3352033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:09:28

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

10 SEP 2020 17:08

PC Open Date & Time

10 SEP 2020 16:53

PC Close Date & Time

10 SEP 2020 19:23

US3352033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:09:28

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

10 SEP 2020 23:16

PC Open Date & Time

10 SEP 2020 20:18

PC Close Date & Time

11 SEP 2020 11:59

US3352033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:09:28

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

12 SEP 2020 04:16

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3352033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 SEP 2020 06:14

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3352033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:09:28

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

13 SEP 2020 12:48

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3352033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:09:28

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3352033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:09:28

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

15 SEP 2020 12:01

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3352033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:09:28

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

16 SEP 2020 12:34

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:09:28

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 ☐

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:09:28

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

No ☒

Yes ☐

PC Time stamp	10 SEP 2020 17:08
PC Open Date & Time	10 SEP 2020 16:53
PC Close Date & Time	10 SEP 2020 19:23

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:09:28

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 ☐

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:09:28

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

No ☒

Yes ☐

PC Time stamp	10 SEP 2020 23:17
PC Open Date & Time	10 SEP 2020 20:18
PC Close Date & Time	11 SEP 2020 11:59

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:09:28

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 ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:09:28

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 04:17
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:09:28

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

99 of 2191

EAB) (1725)

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:09:28

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 06:14
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:09:28

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

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EAB) (1725)

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:09:28

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 12:49
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

DAY 5

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:09:28

Yes ☐

PC Time stamp

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:09:28

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 ☒

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:09:28

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 12:02
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:09:28

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 ☒

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:09:28

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 12:34
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3352033

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 19:57:04

Generated On: 09 Jun 2021 17:09:28

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 18 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3352033

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 19:57:04

Generated On: 09 Jun 2021 17:09:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352033

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 19:57:04

Generated On: 09 Jun 2021 17:09:28

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3352033

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 19:57:04

Generated On: 09 Jun 2021 17:09:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352033

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 19:57:04

Generated On: 09 Jun 2021 17:09:28

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 1 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3352033

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 19:57:04

Generated On: 09 Jun 2021 17:09:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352033

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 19:57:05

Generated On: 09 Jun 2021 17:09:28

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

Visit date (dd MMM yyyy)	08 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
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US3352033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 19:57:05

Generated On: 09 Jun 2021 17:09:28

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	08 OCT 2020
Time of assessment (00:00-23:59)	14:49 (24 HR)
Vital Signs Date and Time (derived)	08 OCT 2020 14:49
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)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3352033

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 19:57:05

Generated On: 09 Jun 2021 17:09:28

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.

US3352033

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 19:57:05

Generated On: 09 Jun 2021 17:09:28

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	08 OCT 2020
Collection time (00:00-23:59)	14:52 (24 HR)
Collection date and time (derived)	08 OCT 2020 14:52

US3352033

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 19:57:05

Generated On: 09 Jun 2021 17:09:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 OCT 2020 08:03:21

Patient Cloud Open Date & Time

06 OCT 2020 00:01

Patient Cloud Close Date & Time

10 OCT 2020 23:59

US3352033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

15 OCT 2020 15:02:34

Patient Cloud Open Date & Time

13 OCT 2020 00:01

Patient Cloud Close Date & Time

17 OCT 2020 23:59

US3352033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

22 OCT 2020 12:58:12

Patient Cloud Open Date & Time

20 OCT 2020 00:01

Patient Cloud Close Date & Time

24 OCT 2020 23:59

US3352033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 NOV 2020 07:06:55
Patient Cloud Open Date & Time	03 NOV 2020 00:01
Patient Cloud Close Date & Time	07 NOV 2020 23:59

US3352033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 NOV 2020 10:11:41

Patient Cloud Open Date & Time

10 NOV 2020 00:01

Patient Cloud Close Date & Time

14 NOV 2020 23:59

US3352033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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 <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°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="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"/>

US3352033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

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

Date and time of submission

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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	21 NOV 2020 13:59:17
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

30 NOV 2020 12:25:18

Patient Cloud Open Date & Time

28 NOV 2020 00:01

Patient Cloud Close Date & Time

02 DEC 2020 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 DEC 2020 08:02:41

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 DEC 2020 07:08:49
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

21 DEC 2020 10:25:27

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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 08:31:35

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

02 JAN 2021 08:19:20

Patient Cloud Open Date & Time

02 JAN 2021 00:01

Patient Cloud Close Date & Time

06 JAN 2021 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

09 JAN 2021 08:01:37

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

18 JAN 2021 14:37:39

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

25 JAN 2021 12:40:51

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

02 FEB 2021 10:45:39

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

10 FEB 2021 11:59:20

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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	17 FEB 2021 17:23:56
Patient Cloud Open Date & Time	13 FEB 2021 00:01
Patient Cloud Close Date & Time	17 FEB 2021 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

22 FEB 2021 12:24:55

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

01 MAR 2021 12:08:07

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

06 MAR 2021 09:12:15

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

DAY 222

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

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

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

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

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

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

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

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

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

[Patient Cloud Close Date & Time](#)

17 MAR 2021 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

DAY 229

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

[Patient Cloud Close Date & Time](#)

24 MAR 2021 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

27 MAR 2021 00:14:19

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 APR 2021 14:00:50

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

10 APR 2021 08:49:46

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

19 APR 2021 12:34:41

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

27 APR 2021 13:34:53

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

DAY 271

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 MAY 2021 12:58:46

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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 ☐

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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"/>

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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"/>

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

DAY 306

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

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

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

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

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

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

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

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

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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"/>

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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 ☐

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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="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"/>

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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="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"/>

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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"/>

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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 <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"/>

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

DAY 376

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

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

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

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

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

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

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

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

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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 ☐

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

DAY 390

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

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

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

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

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

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

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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"/>

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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 ☐

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2021 00:01
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Patient Cloud Close Date & Time	29 SEP 2021 23:59
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US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01
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Patient Cloud Close Date & Time	06 OCT 2021 23:59
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US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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 <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"/>

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	09 OCT 2021 00:01
Patient Cloud Close Date & Time	13 OCT 2021 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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"/>

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	30 OCT 2021 00:01
Patient Cloud Close Date & Time	03 NOV 2021 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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 ☐

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
Patient Cloud Close Date & Time	22 DEC 2021 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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 ☐

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
Patient Cloud Close Date & Time	29 DEC 2021 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JAN 2022 00:01
Patient Cloud Close Date & Time	05 JAN 2022 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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 ☐

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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 ☐

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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 ☐

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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 ☐

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	29 JAN 2022 00:01
Patient Cloud Close Date & Time	02 FEB 2022 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 FEB 2022 00:01
Patient Cloud Close Date & Time	09 FEB 2022 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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 ☐

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

[Patient Cloud Open Date & Time](#)

12 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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 ☐

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

[Patient Cloud Open Date & Time](#)

19 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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 ☐

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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 ☐

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 MAR 2022 00:01
Patient Cloud Close Date & Time	16 MAR 2022 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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 ☐

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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"/>

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 MAR 2022 00:01
Patient Cloud Close Date & Time	30 MAR 2022 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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="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"/>

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	09 APR 2022 00:01
Patient Cloud Close Date & Time	13 APR 2022 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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"/>

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 APR 2022 00:01
Patient Cloud Close Date & Time	20 APR 2022 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

Patient Cloud Open Date & Time	23 APR 2022 00:01
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Patient Cloud Close Date & Time	27 APR 2022 23:59
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US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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="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"/>

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

[Patient Cloud Open Date & Time](#)

07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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"/>

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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="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"/>

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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 ☐

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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="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"/>

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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 ☐

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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 ☐

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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"/>

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

[Patient Cloud Open Date & Time](#)

25 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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"/>

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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 ☐

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	09 JUL 2022 00:01
Patient Cloud Close Date & Time	13 JUL 2022 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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 ☐

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

[Patient Cloud Open Date & Time](#)

23 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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"/>

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

[Patient Cloud Close Date & Time](#)

17 AUG 2022 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

DAY 747

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

[Patient Cloud Open Date & Time](#)

20 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

DAY 754

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

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

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

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

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

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

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

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

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

[Patient Cloud Open Date & Time](#)

27 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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="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"/>

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2022 00:01
Patient Cloud Close Date & Time	07 SEP 2022 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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"/>

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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 <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"/>

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

[Patient Cloud Open Date & Time](#)

17 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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 <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"/>

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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 <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"/>

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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"/>

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

US3352033

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:09:28

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		01 MAR 2021 12:08:23

US3352033

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 19:57:04

Generated On: 09 Jun 2021 17:09:28

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 6 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3352033

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 19:57:04

Generated On: 09 Jun 2021 17:09:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352033

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 19:57:04

Generated On: 09 Jun 2021 17:09:28

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3352033

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 19:57:04

Generated On: 09 Jun 2021 17:09:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352033

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 19:57:04

Generated On: 09 Jun 2021 17:09:28

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3352033

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 19:57:04

Generated On: 09 Jun 2021 17:09:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352033

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 19:57:04

Generated On: 09 Jun 2021 17:09:28

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 6 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3352033

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 19:57:04

Generated On: 09 Jun 2021 17:09:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352033

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 19:57:05

Generated On: 09 Jun 2021 17:09:28

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

Visit date (dd MMM yyyy)	3 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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US3352033

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 19:57:05

Generated On: 09 Jun 2021 17:09:28

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	3 MAR 2021
Time of assessment (00:00-23:59)	12:39 (24 HR)
Vital Signs Date and Time (derived)	3 MAR 2021 12:39
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	145 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3352033

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 19:57:05

Generated On: 09 Jun 2021 17:09:28

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.

US3352033

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 19:57:05

Generated On: 09 Jun 2021 17:09:28

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

Collection date (dd MMM yyyy)	3 MAR 2021
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Collection time (00:00-23:59)	12:59 (24 HR)
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Collection date and time (derived)	3 MAR 2021 12:59
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US3352033

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 19:57:05

Generated On: 09 Jun 2021 17:09:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352033

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 19:57:04

Generated On: 09 Jun 2021 17:09:28

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3352033

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 19:57:04

Generated On: 09 Jun 2021 17:09:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352033

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:28

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

US3352033

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:28

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3352033

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:09:28

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"/>

US3352033

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:09:28

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3352033

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

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 19:57:03

Generated On: 09 Jun 2021 17:09:28

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

Visit date (dd MMM yyyy)	06 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3352033

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

Form: Unblinding

Data signed: (b) (4) 26 Apr 2021 19:57:03

Generated On: 09 Jun 2021 17:09:28

Date of updated informed consent (<i>dd MMM yyyy</i>)	06 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	06 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3352033

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 26 Apr 2021 19:57:03

Generated On: 09 Jun 2021 17:09:28

Height	181 cm
Weight	104.0 kg
BMI (xxx.x)	31.74506

US3352033

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Apr 2021 19:57:03

Generated On: 09 Jun 2021 17:09:28

Height	181 cm
Weight	104.0 kg
BMI (xxx.x)	31.74506
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)	06 JAN 2021
Time of assessment (00:00-23:59)	13:10 (24 HR)
Vital Signs Date and Time (derived)	06 JAN 2021 13:10
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3352033

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Apr 2021 19:57:03

Generated On: 09 Jun 2021 17:09:28

Height	181 cm
Weight	104.0 kg
BMI (xxx.x)	31.74506
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)	06 JAN 2021
Time of assessment (00:00-23:59)	14:26 (24 HR)
Vital Signs Date and Time (derived)	06 JAN 2021 14:26
Temperature (xxx.x)	37.3 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3352033

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

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 19:57:03

Generated On: 09 Jun 2021 17:09:28

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

06 JAN 2021

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

US3352033

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

Form: Exposure

Data signed: (b) (4) 26 Apr 2021 19:57:03

Generated On: 09 Jun 2021 17:09:28

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 06 JAN 2021

What was the treatment time? (00:00-23:59) 13:56 (24 HR)

Treatment Date and Time (derived) 06 JAN 2021 13:56

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

US3352033

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 19:57:03

Generated On: 09 Jun 2021 17:09:28

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

Collection date (dd MMM yyyy)	06 JAN 2021
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Collection time (00:00-23:59)	13:42 (24 HR)
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Collection date and time (derived)	06 JAN 2021 13:42
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US3352033

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 26 Apr 2021 19:57:03

Generated On: 09 Jun 2021 17:09:28

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	06 JAN 2021
Collection time (00:00 - 23:59)	13:38
Collection Date and Time (derived)	06 JAN 2021 13:38

US3352033

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

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 19:57:03

Generated On: 09 Jun 2021 17:09:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352033

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 19:57:04

Generated On: 09 Jun 2021 17:09:28

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3352033

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 19:57:04

Generated On: 09 Jun 2021 17:09:28

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

US3352033

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 19:57:02

Generated On: 09 Jun 2021 17:09:28

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

Visit date (dd MMM yyyy)	03 FEB 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	OLD29
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US3352033

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Apr 2021 19:57:02

Generated On: 09 Jun 2021 17:09:28

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)	03 FEB 2021
Time of assessment (00:00-23:59)	13:25 (24 HR)
Vital Signs Date and Time (derived)	03 FEB 2021 13:25
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3352033

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Apr 2021 19:57:02

Generated On: 09 Jun 2021 17:09:28

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)	03 FEB 2021
Time of assessment (00:00-23:59)	14:25 (24 HR)
Vital Signs Date and Time (derived)	03 FEB 2021 14:25
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)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3352033

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 19:57:02

Generated On: 09 Jun 2021 17:09:28

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.

US3352033

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 26 Apr 2021 19:57:02

Generated On: 09 Jun 2021 17:09:28

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 03 FEB 2021

What was the treatment time? (00:00-23:59) 13:55 (24 HR)

Treatment Date and Time (derived) 03 FEB 2021 13:55

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

US3352033

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 19:57:02

Generated On: 09 Jun 2021 17:09:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352033

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 19:57:04

Generated On: 09 Jun 2021 17:09:28

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3352033

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 19:57:04

Generated On: 09 Jun 2021 17:09:28

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3352033

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 19:57:02

Generated On: 09 Jun 2021 17:09:28

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

Visit date (dd MMM yyyy)	03 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	OLD57
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US3352033

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 19:57:03

Generated On: 09 Jun 2021 17:09:28

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	03 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	12:39 (24 HR)
Vital Signs Date and Time (derived)	03 MAR 2021 12:39
Temperature (<i>xxx.x</i>)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	66 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	145 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	90 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3352033

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 19:57:02

Generated On: 09 Jun 2021 17:09:28

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.

US3352033

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 19:57:02

Generated On: 09 Jun 2021 17:09:28

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

Collection date (dd MMM yyyy)	03 MAR 2021
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Collection time (00:00-23:59)	12:59 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	03 MAR 2021 12:59
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US3352033

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 26 Apr 2021 19:55:02

Generated On: 09 Jun 2021 17:09:28

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3352033

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Apr 2021 19:55:01

Generated On: 09 Jun 2021 17:09:28

AEID	USA-US066-2020-MRNA-1273-P30 1000004
Adverse event	ACUTE INFERIOR WALL MYOCARDIAL INFARCTION
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)	05 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	05 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input 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)	5 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	10 NOV 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Apr 2021 19:55:01

Generated On: 09 Jun 2021 17:09:28

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

US3352033

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Apr 2021 19:55:01

Generated On: 09 Jun 2021 17:09:28

THE SUBJECT STARTED CHEST
PAINS AT 3 AM ON 05NOV2020.
WENT TO THE ER AND WAS
DIAGNOSED WITH
MYOCARDIAL INFARCTION. HE
REMAINS HOSPITALIZED. THE
SUBJECT REPORTED FEELING
BETTER TODAY, WITH NO
COVID-19 SYMPTOMS.
PENDING MEDICAL RECORDS.

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

US3352033

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 26 Apr 2021 19:55:01

Generated On: 09 Jun 2021 17:09:28

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

US3352033

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 26 Apr 2021 19:55:01

Generated On: 09 Jun 2021 17:09:28

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

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 26 Apr 2021 19:55:02

Generated On: 09 Jun 2021 17:09:28

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

Yes ☒

No ☐

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

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 19:55:02

Generated On: 09 Jun 2021 17:09:28

Name of Medication ADVIL

Prophylaxis Yes ☐
No ☒

Indication MIGRAINES

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 19:55:02

Generated On: 09 Jun 2021 17:09:28

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 19:55:02

Generated On: 09 Jun 2021 17:09:28

Name of Medication ADVIL

Prophylaxis Yes ☐
No ☒

Indication NECK PAIN

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 19:55:02

Generated On: 09 Jun 2021 17:09:28

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2014	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 19:55:02

Generated On: 09 Jun 2021 17:09:28

Name of Medication BRILINTA

Prophylaxis Yes ☒
No ☐

Indication CARDIOVASCULAR
PROPHYLAXIS

Dose per administration 90

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 19:55:02

Generated On: 09 Jun 2021 17:09:28

	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)		05 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 19:55:02

Generated On: 09 Jun 2021 17:09:28

Name of Medication LIPITOR

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 19:55:02

Generated On: 09 Jun 2021 17:09:28

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 19:55:02

Generated On: 09 Jun 2021 17:09:28

Name of Medication METOPROLOL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 12.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 19:55:02

Generated On: 09 Jun 2021 17:09:28

	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)		10 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 19:55:02

Generated On: 09 Jun 2021 17:09:28

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication CARDIOVASCULAR
PROHYLAXIS

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 19:55:02

Generated On: 09 Jun 2021 17:09:28

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

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Apr 2021 19:55:02

Generated On: 09 Jun 2021 17:09:28

Name of Medication LIDOCAINE 2%

Prophylaxis Yes ☐
No ☒

Indication ANGIOPLASTY ANESTHETIC

Dose per administration 1

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

If dose unit is Other, specify VIAL

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Apr 2021 19:55:02

Generated On: 09 Jun 2021 17:09:28

	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)		09 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 09 NOV 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"/>

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 19:55:02

Generated On: 09 Jun 2021 17:09:28

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication PAIN AT INJECTION SITE

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 19:55:02

Generated On: 09 Jun 2021 17:09:28

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		4 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 4 FEB 2021		
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3352033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 26 Apr 2021 19:55:02

Generated On: 09 Jun 2021 17:09:28

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3352033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 26 Apr 2021 19:55:02

Generated On: 09 Jun 2021 17:09:28

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
05 NOV 2020	TWO ANGIOPLASTY WITH STENT	Adverse Event	
09 NOV 2020	TWO ANGIOPLASTY WITH STENT	Adverse Event	
05 NOV 2020	CHEST XRAY	Adverse Event	
05 NOV 2020	TRANSTHORACIC ECHOCARDIOGRAM	Adverse Event	

US3352033

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:09:28

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

US3352033

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:09:28

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 ☐

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Data signed: (b) (4) 26 Apr 2021 19:57:03

Generated On: 09 Jun 2021 17:09:28

SAEID	USA-US066-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	HOWARD
Investigator's Last Name	SCHWARTZ
Site Address: Street	7265 SHERIDAN STREET SUITE 210
Site Address: City	PEMBROKE PINES
Site Address: State	FL
Site Address: Postal Code	33024
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Apr 2021 19:57:03

Generated On: 09 Jun 2021 17:09:28

SAEID	USA-US066-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	HOWARD
Investigator's Last Name	SCHWARTZ
Site Address: Street	7265 SHERIDAN STREET SUITE 210
Site Address: City	PEMBROKE PINES
Site Address: State	FL
Site Address: Postal Code	33024
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	09/NOV/2020 18:08
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

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Data signed: (b) (4) 26 Apr 2021 19:57:03

Generated On: 09 Jun 2021 17:09:28

SAEID	USA-US066-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	HOWARD
Investigator's Last Name	SCHWARTZ
Site Address: Street	7265 SHERIDAN STREET SUITE 210
Site Address: City	PEMBROKE PINES
Site Address: State	FL
Site Address: Postal Code	33024
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	13/NOV/2020 08:12
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Data signed: (b) (4) 26 Apr 2021 19:57:03

Generated On: 09 Jun 2021 17:09:28

SAEID	USA-US066-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	HOWARD
Investigator's Last Name	SCHWARTZ
Site Address: Street	7265 SHERIDAN STREET SUITE 210
Site Address: City	PEMBROKE PINES
Site Address: State	FL
Site Address: Postal Code	33024
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	18/NOV/2020 12:25
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

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Data signed: (b) (4) 26 Apr 2021 19:57:03

Generated On: 09 Jun 2021 17:09:28

SAEID	USA-US066-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	HOWARD
Investigator's Last Name	SCHWARTZ
Site Address: Street	7265 SHERIDAN STREET SUITE 210
Site Address: City	PEMBROKE PINES
Site Address: State	FL
Site Address: Postal Code	33024
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	23/NOV/2020 16:51
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

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form (5)

Data signed: (b) (4) 26 Apr 2021 19:57:03

Generated On: 09 Jun 2021 17:09:28

SAEID	USA-US066-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	HOWARD
Investigator's Last Name	SCHWARTZ
Site Address: Street	7265 SHERIDAN STREET SUITE 210
Site Address: City	PEMBROKE PINES
Site Address: State	FL
Site Address: Postal Code	33024
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	08/DEC/2020 10:05
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form (6)

Data signed: (b) (4) 26 Apr 2021 19:57:03

Generated On: 09 Jun 2021 17:09:28

SAEID	USA-US066-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	HOWARD
Investigator's Last Name	SCHWARTZ
Site Address: Street	7265 SHERIDAN STREET SUITE 210
Site Address: City	PEMBROKE PINES
Site Address: State	FL
Site Address: Postal Code	33024
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	21/DEC/2020 10:52
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

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form (7)

Data signed: (b) (4) 26 Apr 2021 19:57:03

Generated On: 09 Jun 2021 17:09:28

SAEID	USA-US066-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	HOWARD
Investigator's Last Name	SCHWARTZ
Site Address: Street	7265 SHERIDAN STREET SUITE 210
Site Address: City	PEMBROKE PINES
Site Address: State	FL
Site Address: Postal Code	33024
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	26/JAN/2021 14:27
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3352033 (Prod: Research Centers of America - ERG)

US3352033

Form: Participant Creation

Generated On: 09 Jun 2021 17:09:28

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:01:00
User entered 'US3352033'	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 16:19:41

US3352033

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:09:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:29:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Aug 2020 19:36:34

US3352033

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:29:34
User entered '06 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 16:19:42

US3352033

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:09:28

[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 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 18:29:34
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	06 Aug 2020 19:36:34

US3352033

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:09:28

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered 'SCRN'	System	06 Aug 2020 19:36:34

US3352033

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:09:28

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:06:02
User entered (b) (6) 1958'	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 16:19:43

US3352033

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:09:28

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:06:02
User entered '61'	(b) (4), (b) (6)	06 Aug 2020 19:37:29

US3352033

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:09:28

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered 'YEARS'	System	06 Aug 2020 19:37:29

US3352033

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:09:28

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered '61'	System	06 Aug 2020 17:58:56

US3352033

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:09:28

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:06:02
User entered 'Male (M)'	(b) (4), (b) (6)	06 Aug 2020 19:37:29

US3352033

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:09:28

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:06:02
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	06 Aug 2020 19:37:29

US3352033

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:09:28

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:06:02
User entered 'l'	(b) (4), (b) (6)	06 Aug 2020 19:37:29

US3352033

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:09:28

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:06:02
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 19:37:29

US3352033

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:09:28

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:06:02
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 19:37:29

US3352033

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:09:28

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:06:02
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 19:37:29

US3352033

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:09:28

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:06:02
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 19:37:29

US3352033

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:09:28

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:06:02
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 19:37:29

US3352033

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:09:28

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:06:02
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 19:37:29

US3352033

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:09:28

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:06:02
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 19:37:29

US3352033

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:09:28

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:06:02
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 19:37:29

US3352033

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:09:28

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:12:38
User entered '6 Aug 2020'	(b) (4), (b) (6)	06 Aug 2020 17:58:56

US3352033

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered 'Aug 2020'	System	06 Aug 2020 17:58:56

US3352033

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered '2020'	System	06 Aug 2020 17:58:56

US3352033

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:09:28

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:12:38
User entered 'Amendment 1 (1)'	(b) (4), (b) (6)	06 Aug 2020 17:58:56

US3352033

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:12:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Aug 2020 17:58:56

US3352033

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:09:28

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:12:38
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 17:58:56

US3352033

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:09:28

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:12:38
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 17:58:56

US3352033

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:09:28

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:12:38
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 17:58:56

US3352033

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:09:28

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:12:38
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 16:19:42

US3352033

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:09:28

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered 'I'	System	06 Aug 2020 17:59:21

US3352033

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:13:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Aug 2020 17:59:21

US3352033

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:09:28

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
User closed query 'Ventricular Tachycardia per source the date is 10-Nov-2020, this is not medical history because it is after the screening date, please update source. ' (Site from CRA).	(b) (4), (b) (6)	22 Feb 2021 03:04:44
Query 'Ventricular Tachycardia per source the date is 10-Nov-2020, this is not medical history because it is after the screening date, please update source. ' answered with 'This is a medical condition, as per protocol it has to be recorded even if is after the screening day.' (Site from CRA).	(b) (4), (b) (6)	18 Feb 2021 14:28:02
User opened query 'Ventricular Tachycardia per source the date is 10-Nov-2020, this is not medical history because it is after the screening date, please update source. ' (Site from CRA).	(b) (4), (b) (6)	08 Feb 2021 15:20:22
User closed query 'Please clarify medical history dates for Hypertension, Hyperlipidemia, and Ventricular Tachycardia, the dates are after screening date, please update source if this is medical history with dates and enter them in EDC. Should these be AE's?' (Site from CRA).	(b) (4), (b) (6)	08 Feb 2021 15:20:22
Query 'Please clarify medical history dates for Hypertension, Hyperlipidemia, and Ventricular Tachycardia, the dates are after screening date, please update source if this is medical history with dates and enter them in EDC. Should these be AE's?' answered with 'updated' (Site from CRA).	Matthew Muniz (b) (4)	09 Dec 2020 20:37:57
User opened query 'Please clarify medical history dates for Hypertension, Hyperlipidemia, and Ventricular Tachycardia, the dates are after screening date, please update source if this is medical history with dates and enter them in EDC. Should these be AE's?' (Site from CRA).	(b) (4), (b) (6)	03 Dec 2020 17:00:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:14:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Aug 2020 19:37:45

US3352033

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:09:28

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:15:01
User coded data point as SOC: Nervous system disorders, HLG: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 19:39:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 19:39:00
Data point term sent to Coder	System	06 Aug 2020 19:38:33
User entered 'MIGRAINES'	(b) (4), (b) (6)	06 Aug 2020 19:38:02

US3352033

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:15:04
User entered 'UN UNK 2015'	(b) (4), (b) (6)	06 Aug 2020 19:38:02

US3352033

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:09:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:15:07
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 19:38:02

US3352033

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:09:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:15:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Aug 2020 19:38:02

US3352033

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:15:11
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 19:38:02

US3352033

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:09:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:15:13
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 19:38:02

US3352033

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:09:28

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered 'Jan 2015'	System	06 Aug 2020 19:38:02

US3352033

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered '2015'	System	06 Aug 2020 19:38:02

US3352033

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered empty.	System	06 Aug 2020 19:38:02

US3352033

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered empty.	System	06 Aug 2020 19:38:02

US3352033

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:09:28

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:15:22
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Presbyopia, LLT: Presbyopia - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 19:39:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 19:39:00
Data point term sent to Coder	System	06 Aug 2020 19:38:35
User entered 'PRESBYOPIA'	(b) (4), (b) (6)	06 Aug 2020 19:38:18

US3352033

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:15:25
User entered 'UN UNK 2005'	(b) (4), (b) (6)	06 Aug 2020 19:38:18

US3352033

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:09:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:15:27
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 19:38:18

US3352033

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:09:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:15:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Aug 2020 19:38:18

US3352033

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:15:30
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 19:38:18

US3352033

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:09:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:15:31
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 19:38:18

US3352033

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:09:28

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered 'Jan 2005'	System	06 Aug 2020 19:38:18

US3352033

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered '2005'	System	06 Aug 2020 19:38:18

US3352033

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered empty.	System	06 Aug 2020 19:38:18

US3352033

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered empty.	System	06 Aug 2020 19:38:18

US3352033

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:09:28

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:16:03
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Tonsillitis, LLT: Tonsillitis recurrent - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 10:51:21
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 10:51:21
Data point term sent to Coder	System	06 Aug 2020 19:39:37
User entered 'TONSILLITIS (RECURRING)'	(b) (4), (b) (6)	06 Aug 2020 19:38:49

US3352033

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:16:04
User entered 'UN UNK 1963'	(b) (4), (b) (6)	06 Aug 2020 19:38:49

US3352033

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:09:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:16:06
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 19:38:49

US3352033

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:09:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:16:08
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 19:38:49

US3352033

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:16:10
User entered 'UN UNK 1963'	(b) (4), (b) (6)	06 Aug 2020 19:38:49

US3352033

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:09:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:16:13
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 19:38:49

US3352033

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:09:28

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered 'Jan 1963'	System	06 Aug 2020 19:38:49

US3352033

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:09:28

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered '1963'	System	06 Aug 2020 19:38:49

US3352033

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered 'Jan 1963'	System	06 Aug 2020 19:38:49

US3352033

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered '1963'	System	06 Aug 2020 19:38:49

US3352033

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:09:28

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:16:56
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: Lumbar disc herniation - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 10:53:04
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 10:53:04
Data point term sent to Coder	System	06 Aug 2020 19:39:38
User entered 'DISCAL HERNIA L5-L6'	(b) (4), (b) (6)	06 Aug 2020 19:39:22

US3352033

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:16:59
User entered 'UN UNK 2019'	(b) (4), (b) (6)	06 Aug 2020 19:39:22

US3352033

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:09:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:17:02
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 19:39:22

US3352033

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:09:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:17:03
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 19:39:22

US3352033

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:17:05
User entered 'UN UNK 2019'	(b) (4), (b) (6)	06 Aug 2020 19:39:22

US3352033

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:09:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:17:07
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 19:39:22

US3352033

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:09:28

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered 'Jan 2019'	System	06 Aug 2020 19:39:22

US3352033

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:09:28

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered '2019'	System	06 Aug 2020 19:39:22

US3352033

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered 'Jan 2019'	System	06 Aug 2020 19:39:22

US3352033

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered '2019'	System	06 Aug 2020 19:39:22

US3352033

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:09:28

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:17:48
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Foot fracture, LLT: Great toe fracture - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 11:28:11
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 11:28:11
Data point term sent to Coder	System	06 Aug 2020 19:41:44
User entered 'LEFT BIG TOE RISLAL PHALANX FRACTURE'	(b) (4), (b) (6)	06 Aug 2020 19:41:37

US3352033

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:17:49
User entered 'UN UNK 2018'	(b) (4), (b) (6)	06 Aug 2020 19:41:37

US3352033

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:09:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:17:52
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 19:41:37

US3352033

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:09:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:17:54
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 19:41:37

US3352033

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:17:56
User entered 'UN UNK 2018'	(b) (4), (b) (6)	06 Aug 2020 19:41:37

US3352033

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:09:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:18:00
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 19:41:37

US3352033

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:09:28

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered 'Jan 2018'	System	06 Aug 2020 19:41:37

US3352033

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:09:28

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered '2018'	System	06 Aug 2020 19:41:37

US3352033

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered 'Jan 2018'	System	06 Aug 2020 19:41:37

US3352033

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered '2018'	System	06 Aug 2020 19:41:37

US3352033

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:09:28

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:35:04
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Tonsillar therapeutic procedures, PT: Tonsillectomy, LLT: Tonsillectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Aug 2020 19:43:59
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 19:43:59
Data point term sent to Coder	System	06 Aug 2020 19:42:45
User entered 'TONSILLECTOMY'	(b) (4), (b) (6)	06 Aug 2020 19:42:16

US3352033

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:35:04
User entered 'UN UNK 1963'	(b) (4), (b) (6)	06 Aug 2020 19:42:16

US3352033

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:09:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:35:04
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 19:42:16

US3352033

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:09:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:35:04
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 19:42:16

US3352033

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:35:04
User entered 'UN UNK 1963'	(b) (4), (b) (6)	06 Aug 2020 19:42:16

US3352033

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:09:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:35:04
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 19:42:16

US3352033

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:09:28

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered 'Jan 1963'	System	06 Aug 2020 19:42:16

US3352033

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:09:28

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered '1963'	System	06 Aug 2020 19:42:16

US3352033

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered 'Jan 1963'	System	06 Aug 2020 19:42:16

US3352033

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered '1963'	System	06 Aug 2020 19:42:16

US3352033

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:09:28

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:35:04
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Arthrodesis, LLT: Arthrodesis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Aug 2020 16:35:15
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Aug 2020 16:35:15
Data point term sent to Coder	System	06 Aug 2020 19:43:48
User entered 'ARTHRODESIS L5-L6'	(b) (4), (b) (6)	06 Aug 2020 19:43:04

US3352033

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:35:04
User entered 'UN UNK 2019'	(b) (4), (b) (6)	06 Aug 2020 19:43:04

US3352033

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:09:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:35:04
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 19:43:04

US3352033

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:09:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:35:04
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 19:43:04

US3352033

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:35:04
User entered 'UN UNK 2019'	(b) (4), (b) (6)	06 Aug 2020 19:43:04

US3352033

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:09:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:35:04
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 19:43:04

US3352033

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:09:28

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered 'Jan 2019'	System	06 Aug 2020 19:43:04

US3352033

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:09:28

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered '2019'	System	06 Aug 2020 19:43:04

US3352033

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered 'Jan 2019'	System	06 Aug 2020 19:43:04

US3352033

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered '2019'	System	06 Aug 2020 19:43:04

US3352033

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:09:28

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:35:04
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Neck pain, LLT: Neck pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 18:09:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Aug 2020 18:09:26
Data point term sent to Coder	System	13 Aug 2020 18:08:43
User entered 'NECK PAIN'	(b) (4), (b) (6)	13 Aug 2020 18:07:50

US3352033

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:35:04
User entered 'UN UNK 2014'	(b) (4), (b) (6)	13 Aug 2020 18:07:50

US3352033

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:09:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:35:04
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 18:07:50

US3352033

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:09:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:35:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 18:07:50

US3352033

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:35:04
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 18:07:50

US3352033

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:09:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:35:04
User entered '0'	(b) (4), (b) (6)	13 Aug 2020 18:07:50

US3352033

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:09:28

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered 'Jan 2014'	System	13 Aug 2020 18:07:50

US3352033

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:09:28

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered '2014'	System	13 Aug 2020 18:07:50

US3352033

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered empty.	System	13 Aug 2020 18:07:50

US3352033

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered empty.	System	13 Aug 2020 18:07:50

US3352033

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:09:28

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:14:00
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Dec 2020 15:46:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Dec 2020 15:46:47
Data point term sent to Coder	System	07 Dec 2020 15:46:34
User entered 'hyperlipidemia'	Matthew Muniz (b) (4)	07 Dec 2020 15:46:29

US3352033

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:09:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:14:00
User closed query 'Start date is after date of Informed Consent. Please correct.' (Site from System).		08 Dec 2020 16:43:56
User entered '01 Jul 2018' reason for change: Data Entry Error	Matthew Muniz (b) (4)	08 Dec 2020 16:43:56
User opened query 'Start date is after date of Informed Consent. Please correct.' (Site from System).	System	07 Dec 2020 15:46:29
User entered '10 Nov 2020'	Matthew Muniz (b) (4)	07 Dec 2020 15:46:29

US3352033

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:09:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:14:00
User entered '0'	Matthew Muniz (b) (4)	07 Dec 2020 15:46:29

US3352033

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:09:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:14:00
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	07 Dec 2020 15:46:29

US3352033

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:14:00
User entered empty.	Matthew Muniz (b) (4)	07 Dec 2020 15:46:29

US3352033

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:09:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:14:00
User entered '0'	Matthew Muniz (b) (4)	07 Dec 2020 15:46:29

US3352033

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered 'Jul 2018'	System	08 Dec 2020 16:43:56
User entered 'Nov 2020'	System	07 Dec 2020 15:46:29

US3352033

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:09:28

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered '2018'	System	08 Dec 2020 16:43:56
User entered '2020'	System	07 Dec 2020 15:46:29

US3352033

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered empty.	System	07 Dec 2020 15:46:29

US3352033

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered empty.	System	07 Dec 2020 15:46:29

US3352033

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:09:28

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:14:00
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition prior to screening and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 05:24:43
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition prior to screening and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'data updated in con med' (Site from DM).	Matthew Muniz (b) (4)	12 Jan 2021 19:43:39
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition prior to screening and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 12:54:49
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	07 Dec 2020 16:05:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Dec 2020 16:05:49
Data point term sent to Coder	System	07 Dec 2020 16:04:43
User entered 'hypertension'	Matthew Muniz (b) (4)	07 Dec 2020 16:04:16

US3352033

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:09:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:14:00
User entered '01 Jul 2018' reason for change: Data Entry Error	Matthew Muniz (b) (4)	08 Dec 2020 16:44:53
User closed query 'Start date is after date of Informed Consent. Please correct.' (Site from System).		08 Dec 2020 16:44:11
User entered '01 Jul 2020' reason for change: Data Entry Error	Matthew Muniz (b) (4)	08 Dec 2020 16:44:11
User opened query 'Start date is after date of Informed Consent. Please correct.' (Site from System).	System	07 Dec 2020 16:04:16
User entered '10 Nov 2020'	Matthew Muniz (b) (4)	07 Dec 2020 16:04:16

US3352033

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:09:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:14:00
User entered '0'	Matthew Muniz (b) (4)	07 Dec 2020 16:04:16

US3352033

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:09:28

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:14:00
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	07 Dec 2020 16:04:16

US3352033

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:14:00
User entered empty.	Matthew Muniz (b) (4)	07 Dec 2020 16:04:16

US3352033

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:09:28

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 15:14:00
User entered '0'	Matthew Muniz (b) (4)	07 Dec 2020 16:04:16

US3352033

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered 'Jul 2018'	System	08 Dec 2020 16:44:53
User entered 'Jul 2020'	System	08 Dec 2020 16:44:11
User entered 'Nov 2020'	System	07 Dec 2020 16:04:16

US3352033

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered '2018'	System	08 Dec 2020 16:44:53
User entered '2020'	System	07 Dec 2020 16:04:16

US3352033

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered empty.	System	07 Dec 2020 16:04:16

US3352033

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered empty.	System	07 Dec 2020 16:04:16

US3352033

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:43:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Aug 2020 19:44:04

US3352033

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:43:33
User entered '6 Aug 2020'	(b) (4), (b) (6)	06 Aug 2020 19:44:04

US3352033

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:43:33
User entered '11:36'	(b) (4), (b) (6)	06 Aug 2020 19:44:04

US3352033

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered '6 Aug 2020 11:36'	System	06 Aug 2020 19:44:04

US3352033

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:28

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:51:06
User closed query 'Per source document review, the height is noted as 178.7 cm. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	08 Oct 2020 19:51:04
Query 'Per source document review, the height is noted as 178.7 cm. Please reconcile. ' answered with 'updated ' (Site from CRA).	Matthew Muniz (b) (4)	07 Oct 2020 20:45:15
User entered '178.7' cm reason for change: Data Entry Error	Matthew Muniz (b) (4)	07 Oct 2020 20:45:08
DataPoint Un-verified.	(b) (4), (b) (6)	06 Oct 2020 19:43:39
DataPoint Verified.		06 Oct 2020 19:43:33
User opened query 'Per source document review, the height is noted as 178.7 cm. Please reconcile. ' (Site from CRA).		06 Oct 2020 19:42:26
User entered '187.7' cm		06 Aug 2020 19:44:04
DataPoint set to visible.	System	06 Aug 2020 17:59:21

US3352033

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:43:33
User entered '99.8' kg	(b) (4), (b) (6)	06 Aug 2020 19:44:04
DataPoint set to visible.	System	06 Aug 2020 17:59:21

US3352033

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:28

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered '31.25226'	System	07 Oct 2020 20:45:08
Amendment Manager: User entered '28.32709'	System	16 Sep 2020 23:45:40
User entered '28.3'	System	06 Aug 2020 19:44:04
DataPoint set to visible.	System	06 Aug 2020 17:59:21

US3352033

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:28

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered 'kg/m2'	System	06 Aug 2020 19:44:04
DataPoint set to visible.	System	06 Aug 2020 17:59:21

US3352033

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:43:33
User entered missing code ND - Not Done.	(b) (4), (b) (6)	06 Aug 2020 19:44:04

US3352033

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:43:33
User entered 'Oral (Oral)'	(b) (4), (b) (6)	06 Aug 2020 19:44:04

US3352033

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:43:33
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 19:44:04

US3352033

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:43:33
User entered missing code ND - Not Done.	(b) (4), (b) (6)	06 Aug 2020 19:44:04

US3352033

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered 'bpm'	System	06 Aug 2020 19:44:04

US3352033

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:43:33
User entered missing code ND - Not Done.	(b) (4), (b) (6)	06 Aug 2020 19:44:04

US3352033

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered 'breaths/min'	System	06 Aug 2020 19:44:04

US3352033

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:43:33
User entered missing code ND - Not Done.	(b) (4), (b) (6)	06 Aug 2020 19:44:04

US3352033

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered 'mmHg'	System	06 Aug 2020 19:44:04

US3352033

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:43:33
User entered missing code ND - Not Done.	(b) (4), (b) (6)	06 Aug 2020 19:44:04

US3352033

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered 'mmHg'	System	06 Aug 2020 19:44:04

US3352033

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:28

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58

US3352033

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:28

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58

US3352033

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:09:28

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:45:35
User entered 'Yes (Y)' reason for change: Data Entry Error		06 Aug 2020 19:44:24
User entered 'No (N)'		06 Aug 2020 19:44:13

US3352033

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:09:28

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:45:35
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	11 Sep 2020 22:08:39
User opened query 'The Physical Examination Date isSystem prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		11 Sep 2020 18:18:28
User entered '6 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Aug 2020 19:44:24
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 19:44:13

US3352033

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:46:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Aug 2020 19:45:15

US3352033

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:46:12
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 19:45:15

US3352033

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:28

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:46:12
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 19:45:15

US3352033

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:28

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:46:12
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 19:45:15

US3352033

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:46:12
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 19:45:15

US3352033

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:28

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:46:12
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 19:45:15

US3352033

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:28

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:46:12
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 19:45:15

US3352033

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:28

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:46:12
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 19:45:15

US3352033

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:28

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:46:12
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 19:45:15

US3352033

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:28

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:46:12
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 19:45:15

US3352033

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:28

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:46:12
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 19:45:15

US3352033

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:28

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:46:12
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 19:45:15

US3352033

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:28

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:46:12
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 19:45:15

US3352033

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:28

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 19:45:15

US3352033

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:46:12
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 19:45:15

US3352033

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:28

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:46:12
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 19:45:15

US3352033

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:28

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:46:12
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 19:45:15

US3352033

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:28

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:46:12
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 19:45:15

US3352033

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:46:12
User entered 'l'	(b) (4), (b) (6)	06 Aug 2020 19:45:15

US3352033

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:28

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 19:45:15

US3352033

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:09:28

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:46:12
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 19:45:15

US3352033

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:09:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:49:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Aug 2020 19:45:24

US3352033

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:49:46
User entered '6 Aug 2020'	(b) (4), (b) (6)	06 Aug 2020 19:45:24

US3352033

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:09:28

[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 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 19:49:46
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	06 Aug 2020 19:45:24

US3352033

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:09:28

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered 'VISIT1'	System	06 Aug 2020 19:45:24

US3352033

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 20:00:41
User entered '06 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 16:49:35

US3352033

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:09:28

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 20:00:41
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 02:33:33
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:33:33
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	06 Aug 2020 16:49:35
User entered '101596' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 16:49:35

US3352033

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 20:00:41
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 16:49:35

US3352033

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 20:00:41
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 19:45:36

US3352033

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 20:00:41
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 19:45:36

US3352033

Folder: Visit 1 Day 1

Form: Randomization

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 20:00:41
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 19:45:36

US3352033

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:09:28

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 20:00:41
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 19:45:36

US3352033

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:09:28

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 20:00:41
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 19:45:36

US3352033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:09:28

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 14:34:36
User entered missing code ND - Not Done.	(b) (4), (b) (6)	06 Aug 2020 19:47:11

US3352033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:09:28

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 14:34:36
User entered missing code ND - Not Done.	(b) (4), (b) (6)	06 Aug 2020 19:47:11

US3352033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:09:28

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 14:34:36
User entered missing code ND - Not Done.	(b) (4), (b) (6)	06 Aug 2020 19:47:11

US3352033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:09:28

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 14:34:36
User entered missing code ND - Not Done.	(b) (4), (b) (6)	06 Aug 2020 19:47:11

US3352033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:28

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	06 Aug 2020 19:47:11

US3352033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 14:34:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Aug 2020 19:47:11

US3352033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 14:34:36
User entered '6 Aug 2020'	(b) (4), (b) (6)	06 Aug 2020 19:47:11

US3352033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 14:34:36
User entered '11:36'	(b) (4), (b) (6)	06 Aug 2020 19:47:11

US3352033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered '6 Aug 2020 11:36'	System	06 Aug 2020 19:47:11

US3352033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 14:34:36
User entered '36.9' C	(b) (4), (b) (6)	06 Aug 2020 19:47:11

US3352033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 14:34:36
User entered 'Oral (Oral)'	(b) (4), (b) (6)	06 Aug 2020 19:47:11

US3352033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 14:34:36
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 19:47:11

US3352033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 14:34:36
User entered '73'	(b) (4), (b) (6)	06 Aug 2020 19:47:11

US3352033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered 'bpm'	System	06 Aug 2020 19:47:11

US3352033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 14:34:36
User entered '14'	(b) (4), (b) (6)	06 Aug 2020 19:47:11

US3352033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered 'breaths/min'	System	06 Aug 2020 19:47:11

US3352033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 14:34:36
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	10 Aug 2020 11:01:34
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Not Clinically significant. Vitals were repeated 10 min later and recorded on unscheduled vitals' (Site from System).	(b) (4), (b) (6)	06 Aug 2020 19:48:59
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	06 Aug 2020 19:47:11
User entered '158'	(b) (4), (b) (6)	06 Aug 2020 19:47:11

US3352033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered 'mmHg'	System	06 Aug 2020 19:47:11

US3352033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 14:34:36
User entered '88'	(b) (4), (b) (6)	06 Aug 2020 19:47:11

US3352033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered 'mmHg'	System	06 Aug 2020 19:47:11

US3352033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

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[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 14:34:36
User entered missing code ND - Not Done.	(b) (4), (b) (6)	06 Aug 2020 19:47:11

US3352033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:09:28

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 14:34:36
User entered missing code ND - Not Done.	(b) (4), (b) (6)	06 Aug 2020 19:47:11

US3352033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:28

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	06 Aug 2020 19:47:11

US3352033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 14:34:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Aug 2020 19:47:11

US3352033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 14:34:36
User entered '6 Aug 2020'	(b) (4), (b) (6)	06 Aug 2020 19:47:11

US3352033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 14:34:36
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 09:05:57
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 19:47:46
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 19:47:11
User entered '13:50'	(b) (4), (b) (6)	06 Aug 2020 19:47:11

US3352033

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Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered '6 Aug 2020 13:50'	System	06 Aug 2020 19:47:11

US3352033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 14:34:36
User closed query 'Data is required. Please provide.' (Site from System).	System	06 Aug 2020 19:47:41
Query 'Data is required. Please provide.' answered by System data change (Site from System).		06 Aug 2020 19:47:41
User entered '36.5' C reason for change: Data Entry Error	(b) (4), (b) (6)	06 Aug 2020 19:47:41
User opened query 'Data is required. Please provide.' (Site from System).	System	06 Aug 2020 19:47:11
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 19:47:11

US3352033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 14:34:36
User closed query 'Data is required. Please provide.' (Site from System).	System	06 Aug 2020 19:47:51
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Aug 2020 19:47:51
User opened query 'Data is required. Please provide.' (Site from System).	System	06 Aug 2020 19:47:11
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 19:47:11

US3352033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 14:34:36
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 19:47:11

US3352033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 14:34:36
User entered '69'	(b) (4), (b) (6)	06 Aug 2020 19:47:11

US3352033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

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[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered 'bpm'	System	06 Aug 2020 19:47:11

US3352033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 14:34:36
User entered '16'	(b) (4), (b) (6)	06 Aug 2020 19:47:11

US3352033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered 'breaths/min'	System	06 Aug 2020 19:47:11

US3352033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 14:34:36
User entered '152'	(b) (4), (b) (6)	06 Aug 2020 19:47:11

US3352033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered 'mmHg'	System	06 Aug 2020 19:47:11

US3352033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 14:34:36
User entered '88'	(b) (4), (b) (6)	06 Aug 2020 19:47:11

US3352033

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered 'mmHg'	System	06 Aug 2020 19:47:11

US3352033

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:09:28

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 14:34:43
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 19:50:25

US3352033

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:09:28

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 14:34:43
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 19:50:25

US3352033

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:09:28

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 14:35:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Aug 2020 18:00:55

US3352033

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:09:28

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 14:35:10
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 18:00:55

US3352033

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 14:35:10
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 18:00:55

US3352033

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:09:28

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered 'MRNA-1273 OR PLACEBO'	System	06 Aug 2020 18:00:55

US3352033

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:09:28

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 14:35:10
User entered '6 Aug 2020'	(b) (4), (b) (6)	06 Aug 2020 18:00:55

US3352033

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:09:28

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 14:35:10
User entered '13:20'	(b) (4), (b) (6)	06 Aug 2020 18:00:55

US3352033

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:09:28

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered '6 Aug 2020 13:20'	System	06 Aug 2020 18:00:55

US3352033

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:09:28

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 14:35:10
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	06 Aug 2020 18:00:55

US3352033

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:09:28

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 14:35:10
User entered 'ONCE'	System	06 Aug 2020 18:00:55

US3352033

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:09:28

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered 'INTRAMUSCULAR'	System	06 Aug 2020 18:00:55

US3352033

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 14:35:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Aug 2020 19:51:14

US3352033

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:28

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 14:35:39
User entered '6 Aug 2020'	(b) (4), (b) (6)	06 Aug 2020 19:51:14

US3352033

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:28

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 14:35:39
User entered '12:39'	(b) (4), (b) (6)	06 Aug 2020 19:51:14

US3352033

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:28

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered '6 Aug 2020 12:39'	System	06 Aug 2020 19:51:14

US3352033

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:09:28

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 14:38:13
User entered '6 Aug 2020'	(b) (4), (b) (6)	06 Aug 2020 19:51:27

US3352033

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:09:28

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	06 Aug 2020 19:51:27

US3352033

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:09:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:02:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Aug 2020 19:51:27

US3352033

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:09:28

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:02:21
User entered '12:04'	(b) (4), (b) (6)	06 Aug 2020 19:51:27

US3352033

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:09:28

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered '6 Aug 2020 12:04'	System	06 Aug 2020 19:51:27

US3352033

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:09:28

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	06 Aug 2020 19:51:27

US3352033

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:09:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:02:21
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 19:51:27

US3352033

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:09:28

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:02:21
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 19:51:27

US3352033

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:09:28

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered empty.	System	06 Aug 2020 19:51:27

US3352033

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:09:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 14:38:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Aug 2020 19:50:35

US3352033

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:09:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered 'I'	System	06 Aug 2020 19:50:35

US3352033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
Data entry locked.	System	06 Aug 2020 18:00:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 18:00:55

US3352033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:09:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-06T14:06:31', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '662fbce5-de39-46b5-a389-077f6489725f' User entered 'Yes (Y)'	System	06 Aug 2020 18:07:04
	System	06 Aug 2020 18:07:04

US3352033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:09:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-06T14:06:40', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '662fbce5-de39-46b5-a389-077f6489725f' User entered '97.0'	System	06 Aug 2020 18:07:04
	System	06 Aug 2020 18:07:04

US3352033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-06T14:06:44', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '662fbce5-de39-46b5-a389-077f6489725f' User entered 'No (N)'	System	06 Aug 2020 18:07:04
	System	06 Aug 2020 18:07:04

US3352033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:09:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-06T14:06:58', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '662fbce5-de39-46b5-a389-077f6489725f' User entered '06 Aug 2020 14:06'	System	06 Aug 2020 18:07:04
	System	06 Aug 2020 18:07:04

US3352033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:09:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '06 Aug 2020 13:40'	System	06 Aug 2020 18:00:55

US3352033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:09:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '06 Aug 2020 16:10'	System	06 Aug 2020 18:00:55

US3352033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
Data entry locked.	System	06 Aug 2020 18:00:55
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 18:00:55

US3352033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:09:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-06T20:27:17', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'c4cee52b-4656-481d-9b4c-3251ade32012' User entered 'Yes (Y)'	System	07 Aug 2020 00:27:46
	System	07 Aug 2020 00:27:46

US3352033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:09:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-06T20:27:27', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'c4cee52b-4656-481d-9b4c-3251ade32012' User entered '98.0'	System	07 Aug 2020 00:27:46
	System	07 Aug 2020 00:27:46

US3352033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-06T20:27:30', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'c4cee52b-4656-481d-9b4c-3251ade32012' User entered 'No (N)'	System	07 Aug 2020 00:27:46
	System	07 Aug 2020 00:27:46

US3352033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:09:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-06T20:27:42', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'c4cee52b-4656-481d-9b4c-3251ade32012' User entered '06 Aug 2020 20:27'	System	07 Aug 2020 00:27:46
	System	07 Aug 2020 00:27:46

US3352033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:09:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '06 Aug 2020 17:05'	System	06 Aug 2020 18:00:55

US3352033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:09:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 18:00:55

US3352033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
Data entry locked.	System	06 Aug 2020 18:00:55
User entered 'Day 2'	System	06 Aug 2020 18:00:55

US3352033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:09:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-07T12:00:35', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '2ff106b4-f52b-4cd0-bd09-c658fbeaad9e' User entered 'Yes (Y)'	System	07 Aug 2020 16:00:55
	System	07 Aug 2020 16:00:55

US3352033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:09:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-07T12:00:42', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '2ff106b4-f52b-4cd0-bd09-c658fbeaad9e' User entered '98.1'	System	07 Aug 2020 16:00:55
	System	07 Aug 2020 16:00:55

US3352033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-07T12:00:46', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '2ff106b4-f52b-4cd0-bd09-c658fbeaad9e'	System	07 Aug 2020 16:00:55
User entered 'No (N)'	System	07 Aug 2020 16:00:55

US3352033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:09:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-07T12:00:50', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '2ff106b4-f52b-4cd0-bd09-c658fbeaad9e'	System	07 Aug 2020 16:00:55
User entered '07 Aug 2020 12:00'	System	07 Aug 2020 16:00:55

US3352033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:09:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 18:00:55

US3352033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:09:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 18:00:55

US3352033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
Data entry locked.	System	06 Aug 2020 18:00:55
User entered 'Day 3'	System	06 Aug 2020 18:00:55

US3352033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:09:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-08T18:44:19', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'eb34f2fd-0634-4e8f-a496-21a0a29ec869' User entered 'Yes (Y)'	System	08 Aug 2020 22:44:43
	System	08 Aug 2020 22:44:43

US3352033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:09:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-08T18:44:29', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'eb34f2fd-0634-4e8f-a496-21a0a29ec869' User entered '98.2'	System	08 Aug 2020 22:44:43
	System	08 Aug 2020 22:44:43

US3352033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-08T18:44:34', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'eb34f2fd-0634-4e8f-a496-21a0a29ec869'	System	08 Aug 2020 22:44:43
User entered 'No (N)'	System	08 Aug 2020 22:44:43

US3352033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:09:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-08T18:44:41', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'eb34f2fd-0634-4e8f-a496-21a0a29ec869' User entered '08 Aug 2020 18:44'	System	08 Aug 2020 22:44:43
	System	08 Aug 2020 22:44:43

US3352033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:09:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 18:00:55

US3352033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:09:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 18:00:55

US3352033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
Data entry locked.	System	06 Aug 2020 18:00:55
User entered 'Day 4'	System	06 Aug 2020 18:00:55

US3352033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:09:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-10T10:09:33', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '93ebf903-afb7-4ba2-89d3-163ce60b335b' User entered 'Yes (Y)'	System	10 Aug 2020 14:09:57
	System	10 Aug 2020 14:09:57

US3352033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:09:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-10T10:09:44', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '93ebf903-afb7-4ba2-89d3-163ce60b335b' User entered '98.4'	System	10 Aug 2020 14:09:57
	System	10 Aug 2020 14:09:57

US3352033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-10T10:09:47', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '93ebf903-afb7-4ba2-89d3-163ce60b335b' User entered 'No (N)'	System	10 Aug 2020 14:09:57
	System	10 Aug 2020 14:09:57

US3352033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:09:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-10T10:09:51', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '93ebf903-afb7-4ba2-89d3-163ce60b335b' User entered '10 Aug 2020 10:09'	System	10 Aug 2020 14:09:57
	System	10 Aug 2020 14:09:57

US3352033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:09:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 18:00:55

US3352033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:09:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 18:00:55

US3352033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
Data entry locked.	System	06 Aug 2020 18:00:55
User entered 'Day 5'	System	06 Aug 2020 18:00:55

US3352033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:09:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24

US3352033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:09:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24

US3352033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24

US3352033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24

US3352033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:09:28

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24

US3352033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:09:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24

US3352033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:09:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 18:00:55

US3352033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:09:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 18:00:55

US3352033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
Data entry locked.	System	06 Aug 2020 18:00:55
User entered 'Day 6'	System	06 Aug 2020 18:00:55

US3352033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:09:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-11T18:31:07', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '4a06f4c5-cab6-492c-ab19-8d5f88381cce' User entered 'Yes (Y)'	System	11 Aug 2020 22:31:40
	System	11 Aug 2020 22:31:40

US3352033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:09:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-11T18:31:13', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '4a06f4c5-cab6-492c-ab19-8d5f88381cce' User entered '98.6'	System	11 Aug 2020 22:31:40
	System	11 Aug 2020 22:31:40

US3352033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-11T18:31:19', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '4a06f4c5-cab6-492c-ab19-8d5f88381cce' User entered 'Yes (Y)'	System	11 Aug 2020 22:31:40
	System	11 Aug 2020 22:31:40

US3352033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User closed query 'DM RQ: Please provide the corresponding conmed record number.' (Site from DM).	(b) (4), (b) (6)	21 Aug 2020 16:12:29
Query 'DM RQ: Please provide the corresponding conmed record number.' answered with '#2 ' (Site from DM).	(b) (4), (b) (6)	19 Aug 2020 17:21:55
User opened query 'DM RQ: Please provide the corresponding conmed record number.' (Site from DM).	(b) (4), (b) (6)	17 Aug 2020 14:21:45
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).	(b) (4), (b) (6)	17 Aug 2020 14:19:21
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 DETAILS WERE RECORDED ' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 19:57:39
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).	System	11 Aug 2020 22:31:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-11T18:31:31', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '4a06f4c5-cab6-492c-ab19-8d5f88381cce'	System	11 Aug 2020 22:31:40
User entered '1'	System	11 Aug 2020 22:31:40

US3352033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:09:28

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-11T18:31:31', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '4a06f4c5-cab6-492c-ab19-8d5f88381cce' User entered '0'	System	11 Aug 2020 22:31:40
	System	11 Aug 2020 22:31:40

US3352033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:09:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-11T18:31:37', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '4a06f4c5-cab6-492c-ab19-8d5f88381cce' User entered '11 Aug 2020 18:31'	System	11 Aug 2020 22:31:40
	System	11 Aug 2020 22:31:40

US3352033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:09:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 18:00:55

US3352033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:09:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 18:00:55

US3352033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
Data entry locked.	System	06 Aug 2020 18:00:55
User entered 'Day 7'	System	06 Aug 2020 18:00:55

US3352033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:09:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-12T12:01:29', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '1c2c8538-ab8c-43d8-a501-3fe1fa45964c' User entered 'Yes (Y)'	System	12 Aug 2020 16:01:57
	System	12 Aug 2020 16:01:57

US3352033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:09:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-12T12:01:40', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '1c2c8538-ab8c-43d8-a501-3fe1fa45964c' User entered '98.6'	System	12 Aug 2020 16:01:57
	System	12 Aug 2020 16:01:57

US3352033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-12T12:01:47', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '1c2c8538-ab8c-43d8-a501-3fe1fa45964c'	System	12 Aug 2020 16:01:57
User entered 'No (N)'	System	12 Aug 2020 16:01:57

US3352033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:09:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-12T12:01:54', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '1c2c8538-ab8c-43d8-a501-3fe1fa45964c'	System	12 Aug 2020 16:01:57
User entered '12 Aug 2020 12:01'	System	12 Aug 2020 16:01:57

US3352033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:09:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 18:00:55

US3352033

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:09:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 18:00:55

US3352033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
Data entry locked.	System	06 Aug 2020 18:00:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 18:00:55

US3352033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:09:28

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 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-06T14:07:10', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '5f6ca2b8-31a6-4a01-aca7-a4a057288864' User entered 'None (1)'	System	06 Aug 2020 18:07:33
	System	06 Aug 2020 18:07:33

US3352033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:09:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-06T14:07:14', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '5f6ca2b8-31a6-4a01-aca7-a4a057288864' User entered 'No (N)'	System	06 Aug 2020 18:07:33
	System	06 Aug 2020 18:07:33

US3352033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-06T14:07:18', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '5f6ca2b8-31a6-4a01-aca7-a4a057288864' User entered 'No (N)'	System	06 Aug 2020 18:07:33
	System	06 Aug 2020 18:07:33

US3352033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:09:28

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 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-06T14:07:21', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '5f6ca2b8-31a6-4a01-aca7-a4a057288864' User entered 'None (1)'	System	06 Aug 2020 18:07:33
	System	06 Aug 2020 18:07:33

US3352033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:09:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-06T14:07:27', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '5f6ca2b8-31a6-4a01-aca7-a4a057288864' User entered '06 Aug 2020 14:07'	System	06 Aug 2020 18:07:33
	System	06 Aug 2020 18:07:33

US3352033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:09:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '06 Aug 2020 13:40'	System	06 Aug 2020 18:00:55

US3352033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:09:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '06 Aug 2020 16:10'	System	06 Aug 2020 18:00:55

US3352033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
Data entry locked.	System	06 Aug 2020 18:00:55
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 18:00:55

US3352033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:09:28

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 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-06T20:28:18', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '7c0bf167-0097-4d21-a08f-892f7c5fa034'	System	07 Aug 2020 00:28:33
User entered 'None (1)'	System	07 Aug 2020 00:28:33

US3352033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:09:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-06T20:28:21', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '7c0bf167-0097-4d21-a08f-892f7c5fa034'	System	07 Aug 2020 00:28:33
User entered 'No (N)'	System	07 Aug 2020 00:28:33

US3352033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-06T20:28:24', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '7c0bf167-0097-4d21-a08f-892f7c5fa034'	System	07 Aug 2020 00:28:33
User entered 'No (N)'	System	07 Aug 2020 00:28:33

US3352033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:09:28

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 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-06T20:28:28', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '7c0bf167-0097-4d21-a08f-892f7c5fa034'	System	07 Aug 2020 00:28:33
User entered 'None (1)'	System	07 Aug 2020 00:28:33

US3352033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:09:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-06T20:28:31', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '7c0bf167-0097-4d21-a08f-892f7c5fa034'	System	07 Aug 2020 00:28:33
User entered '06 Aug 2020 20:28'	System	07 Aug 2020 00:28:33

US3352033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:09:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '06 Aug 2020 17:05'	System	06 Aug 2020 18:00:55

US3352033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:09:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 18:00:55

US3352033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
Data entry locked.	System	06 Aug 2020 18:00:55
User entered 'Day 2'	System	06 Aug 2020 18:00:55

US3352033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:09:28

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 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-07T12:00:55', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '891aaccd-ec2a-445d-88c0-4e504883d715'	System	07 Aug 2020 16:01:10
User entered 'None (1)'	System	07 Aug 2020 16:01:10

US3352033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:09:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-07T12:00:59', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '891aaccd-ec2a-445d-88c0-4e504883d715'	System	07 Aug 2020 16:01:10
User entered 'No (N)'	System	07 Aug 2020 16:01:10

US3352033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-07T12:01:01', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '891aaccd-ec2a-445d-88c0-4e504883d715'	System	07 Aug 2020 16:01:10
User entered 'No (N)'	System	07 Aug 2020 16:01:10

US3352033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:09:28

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 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-07T12:01:05', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '891aaccd-ec2a-445d-88c0-4e504883d715'	System	07 Aug 2020 16:01:10
User entered 'None (1)'	System	07 Aug 2020 16:01:10

US3352033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:09:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-07T12:01:07', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '891aaccd-ec2a-445d-88c0-4e504883d715' User entered '07 Aug 2020 12:01'	System	07 Aug 2020 16:01:10
	System	07 Aug 2020 16:01:10

US3352033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:09:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 18:00:55

US3352033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:09:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 18:00:55

US3352033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
Data entry locked.	System	06 Aug 2020 18:00:55
User entered 'Day 3'	System	06 Aug 2020 18:00:55

US3352033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:09:28

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 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-08T18:44:46', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '6afdf203-562a-418a-a1ef-f726b8b774f3'	System	08 Aug 2020 22:45:06
User entered 'None (1)'	System	08 Aug 2020 22:45:06

US3352033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:09:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-08T18:44:49', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '6afdf203-562a-418a-a1ef-f726b8b774f3'	System	08 Aug 2020 22:45:06
User entered 'No (N)'	System	08 Aug 2020 22:45:06

US3352033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-08T18:44:53', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '6afdf203-562a-418a-a1ef-f726b8b774f3'	System	08 Aug 2020 22:45:06
User entered 'No (N)'	System	08 Aug 2020 22:45:06

US3352033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:09:28

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 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-08T18:44:56', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '6afdf203-562a-418a-a1ef-f726b8b774f3'	System	08 Aug 2020 22:45:06
User entered 'None (1)'	System	08 Aug 2020 22:45:06

US3352033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:09:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-08T18:45:00', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '6afdf203-562a-418a-a1ef-f726b8b774f3' User entered '08 Aug 2020 18:45'	System	08 Aug 2020 22:45:06
	System	08 Aug 2020 22:45:06

US3352033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:09:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 18:00:55

US3352033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:09:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 18:00:55

US3352033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
Data entry locked.	System	06 Aug 2020 18:00:55
User entered 'Day 4'	System	06 Aug 2020 18:00:55

US3352033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:09:28

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 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-10T10:09:55', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'a53c365f-2505-46f0-9290-d54dc396a4aa'	System	10 Aug 2020 14:10:12
User entered 'None (1)'	System	10 Aug 2020 14:10:12

US3352033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:09:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-10T10:09:58', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'a53c365f-2505-46f0-9290-d54dc396a4aa'	System	10 Aug 2020 14:10:12
User entered 'No (N)'	System	10 Aug 2020 14:10:12

US3352033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-10T10:10:01', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'a53c365f-2505-46f0-9290-d54dc396a4aa' User entered 'No (N)'	System	10 Aug 2020 14:10:12
	System	10 Aug 2020 14:10:12

US3352033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:09:28

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 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-10T10:10:04', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'a53c365f-2505-46f0-9290-d54dc396a4aa'	System	10 Aug 2020 14:10:12
User entered 'None (1)'	System	10 Aug 2020 14:10:12

US3352033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:09:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-10T10:10:07', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'a53c365f-2505-46f0-9290-d54dc396a4aa' User entered '10 Aug 2020 10:10'	System	10 Aug 2020 14:10:12
	System	10 Aug 2020 14:10:12

US3352033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:09:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 18:00:55

US3352033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:09:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 18:00:55

US3352033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
Data entry locked.	System	06 Aug 2020 18:00:55
User entered 'Day 5'	System	06 Aug 2020 18:00:55

US3352033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:09:28

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 20:11:24

US3352033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:09:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24

US3352033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:09:28

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 20:11:24

US3352033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24

US3352033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:09:28

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 20:11:24

US3352033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:09:28

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 20:11:24

US3352033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:09:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24

US3352033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:09:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 18:00:55

US3352033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:09:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 18:00:55

US3352033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
Data entry locked.	System	06 Aug 2020 18:00:55
User entered 'Day 6'	System	06 Aug 2020 18:00:55

US3352033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:09:28

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 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-11T18:31:42', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '0e957921-0b3f-4ff7-8d0c-3defd51aedda' User entered 'None (1)'	System	11 Aug 2020 22:32:03
	System	11 Aug 2020 22:32:03

US3352033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:09:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-11T18:31:48', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '0e957921-0b3f-4ff7-8d0c-3defd51aedda' User entered 'No (N)'	System	11 Aug 2020 22:32:03
	System	11 Aug 2020 22:32:03

US3352033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-11T18:31:52', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '0e957921-0b3f-4ff7-8d0c-3defd51aedd'	System	11 Aug 2020 22:32:03
User entered 'No (N)'	System	11 Aug 2020 22:32:03

US3352033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:09:28

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 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-11T18:31:55', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '0e957921-0b3f-4ff7-8d0c-3defd51aedd'	System	11 Aug 2020 22:32:03
User entered 'None (1)'	System	11 Aug 2020 22:32:03

US3352033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:09:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-11T18:31:58', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '0e957921-0b3f-4ff7-8d0c-3defd51aedda' User entered '11 Aug 2020 18:31'	System	11 Aug 2020 22:32:03
	System	11 Aug 2020 22:32:03

US3352033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:09:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 18:00:55

US3352033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:09:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 18:00:55

US3352033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
Data entry locked.	System	06 Aug 2020 18:00:55
User entered 'Day 7'	System	06 Aug 2020 18:00:55

US3352033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:09:28

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 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-12T12:01:59', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'a6d92fda-9a1a-49fb-b732-edcb707f413e' User entered 'None (1)'	System	12 Aug 2020 16:02:32
	System	12 Aug 2020 16:02:32

US3352033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:09:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-12T12:02:02', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'a6d92fda-9a1a-49fb-b732-edcb707f413e' User entered 'No (N)'	System	12 Aug 2020 16:02:32
	System	12 Aug 2020 16:02:32

US3352033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-12T12:02:12', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'a6d92fda-9a1a-49fb-b732-edcb707f413e' User entered 'No (N)'	System	12 Aug 2020 16:02:32
	System	12 Aug 2020 16:02:32

US3352033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:09:28

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 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-12T12:02:16', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'a6d92fda-9a1a-49fb-b732-edcb707f413e' User entered 'None (1)'	System	12 Aug 2020 16:02:32
	System	12 Aug 2020 16:02:32

US3352033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:09:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-12T12:02:28', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'a6d92fda-9a1a-49fb-b732-edcb707f413e' User entered '12 Aug 2020 12:02'	System	12 Aug 2020 16:02:32
	System	12 Aug 2020 16:02:32

US3352033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:09:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 18:00:55

US3352033

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:09:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 18:00:55

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
Data entry locked.	System	06 Aug 2020 18:00:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 18:00:55

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:09:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-06T14:07:32', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'b748ef20-12ec-4cf7-b25d-3e161ae6085b' User entered 'None (0)'	System	06 Aug 2020 18:07:54
	System	06 Aug 2020 18:07:54

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:09:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-06T14:07:34', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'b748ef20-12ec-4cf7-b25d-3e161ae6085b' User entered 'None (0)'	System	06 Aug 2020 18:07:54
	System	06 Aug 2020 18:07:54

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:09:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-06T14:07:37', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'b748ef20-12ec-4cf7-b25d-3e161ae6085b' User entered 'None (0)'	System	06 Aug 2020 18:07:54
	System	06 Aug 2020 18:07:54

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:09:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-06T14:07:39', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'b748ef20-12ec-4cf7-b25d-3e161ae6085b' User entered 'None (0)'	System	06 Aug 2020 18:07:54
	System	06 Aug 2020 18:07:54

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:09:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-06T14:07:42', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'b748ef20-12ec-4cf7-b25d-3e161ae6085b' User entered 'None (0)'	System	06 Aug 2020 18:07:54
	System	06 Aug 2020 18:07:54

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:09:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-06T14:07:44', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'b748ef20-12ec-4cf7-b25d-3e161ae6085b' User entered 'None (0)'	System	06 Aug 2020 18:07:54
	System	06 Aug 2020 18:07:54

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:09:28

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 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-06T14:07:48', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'b748ef20-12ec-4cf7-b25d-3e161ae6085b' User entered 'No (N)'	System	06 Aug 2020 18:07:54
	System	06 Aug 2020 18:07:54

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:09:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-06T14:07:51', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'b748ef20-12ec-4cf7-b25d-3e161ae6085b' User entered '06 Aug 2020 14:07'	System	06 Aug 2020 18:07:54
	System	06 Aug 2020 18:07:54

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:09:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '06 Aug 2020 13:40'	System	06 Aug 2020 18:00:55

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:09:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '06 Aug 2020 16:10'	System	06 Aug 2020 18:00:55

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
Data entry locked.	System	06 Aug 2020 18:00:55
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 18:00:55

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:09:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-06T20:27:53', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'c93ed1b3-59ed-4c49-995b-b0bf5052607c' User entered 'None (0)'	System	07 Aug 2020 00:28:13
	System	07 Aug 2020 00:28:13

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:09:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-06T20:27:55', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'c93ed1b3-59ed-4c49-995b-b0bf5052607c' User entered 'None (0)'	System	07 Aug 2020 00:28:13
	System	07 Aug 2020 00:28:13

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:09:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-06T20:27:58', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'c93ed1b3-59ed-4c49-995b-b0bf5052607c' User entered 'None (0)'	System	07 Aug 2020 00:28:13
	System	07 Aug 2020 00:28:13

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:09:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-06T20:28:00', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'c93ed1b3-59ed-4c49-995b-b0bf5052607c' User entered 'None (0)'	System	07 Aug 2020 00:28:13
	System	07 Aug 2020 00:28:13

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:09:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-06T20:28:02', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'c93ed1b3-59ed-4c49-995b-b0bf5052607c' User entered 'None (0)'	System	07 Aug 2020 00:28:13
	System	07 Aug 2020 00:28:13

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:09:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-06T20:28:04', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'c93ed1b3-59ed-4c49-995b-b0bf5052607c' User entered 'None (0)'	System	07 Aug 2020 00:28:13
	System	07 Aug 2020 00:28:13

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:09:28

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 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-06T20:28:07', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'c93ed1b3-59ed-4c49-995b-b0bf5052607c' User entered 'No (N)'	System	07 Aug 2020 00:28:13
	System	07 Aug 2020 00:28:13

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:09:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-06T20:28:11', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'c93ed1b3-59ed-4c49-995b-b0bf5052607c' User entered '06 Aug 2020 20:28'	System	07 Aug 2020 00:28:13
	System	07 Aug 2020 00:28:13

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:09:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '06 Aug 2020 17:05'	System	06 Aug 2020 18:00:55

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:09:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 18:00:55

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
Data entry locked.	System	06 Aug 2020 18:00:55
User entered 'Day 2'	System	06 Aug 2020 18:00:55

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:09:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-07T12:01:12', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '56d92d32-80ca-4e33-9593-8ce58233ff87' User entered 'None (0)'	System	07 Aug 2020 16:01:31
	System	07 Aug 2020 16:01:31

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:09:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-07T12:01:14', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '56d92d32-80ca-4e33-9593-8ce58233ff87' User entered 'None (0)'	System	07 Aug 2020 16:01:31
	System	07 Aug 2020 16:01:31

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:09:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-07T12:01:16', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '56d92d32-80ca-4e33-9593-8ce58233ff87' User entered 'None (0)'	System	07 Aug 2020 16:01:31
	System	07 Aug 2020 16:01:31

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:09:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-07T12:01:21', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '56d92d32-80ca-4e33-9593-8ce58233ff87' User entered 'None (0)'	System	07 Aug 2020 16:01:31
	System	07 Aug 2020 16:01:31

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:09:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-07T12:01:23', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '56d92d32-80ca-4e33-9593-8ce58233ff87' User entered 'None (0)'	System	07 Aug 2020 16:01:31
	System	07 Aug 2020 16:01:31

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:09:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-07T12:01:24', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '56d92d32-80ca-4e33-9593-8ce58233ff87' User entered 'None (0)'	System	07 Aug 2020 16:01:31
	System	07 Aug 2020 16:01:31

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:09:28

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 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-07T12:01:27', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '56d92d32-80ca-4e33-9593-8ce58233ff87'	System	07 Aug 2020 16:01:31
User entered 'No (N)'	System	07 Aug 2020 16:01:31

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:09:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-07T12:01:30', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '56d92d32-80ca-4e33-9593-8ce58233ff87' User entered '07 Aug 2020 12:01'	System	07 Aug 2020 16:01:31
	System	07 Aug 2020 16:01:31

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:09:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 18:00:55

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:09:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 18:00:55

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
Data entry locked.	System	06 Aug 2020 18:00:55
User entered 'Day 3'	System	06 Aug 2020 18:00:55

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:09:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-08T18:45:05', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '75f10f57-3d7b-4866-b342-17b619115ea9' User entered 'None (0)'	System	08 Aug 2020 22:45:22
	System	08 Aug 2020 22:45:22

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:09:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-08T18:45:07', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '75f10f57-3d7b-4866-b342-17b619115ea9' User entered 'None (0)'	System	08 Aug 2020 22:45:22
	System	08 Aug 2020 22:45:22

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:09:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-08T18:45:09', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '75f10f57-3d7b-4866-b342-17b619115ea9' User entered 'None (0)'	System	08 Aug 2020 22:45:22
	System	08 Aug 2020 22:45:22

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:09:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-08T18:45:11', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '75f10f57-3d7b-4866-b342-17b619115ea9' User entered 'None (0)'	System	08 Aug 2020 22:45:22
	System	08 Aug 2020 22:45:22

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:09:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-08T18:45:13', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '75f10f57-3d7b-4866-b342-17b619115ea9' User entered 'None (0)'	System	08 Aug 2020 22:45:22
	System	08 Aug 2020 22:45:22

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:09:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-08T18:45:15', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '75f10f57-3d7b-4866-b342-17b619115ea9' User entered 'None (0)'	System	08 Aug 2020 22:45:22
	System	08 Aug 2020 22:45:22

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:09:28

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 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-08T18:45:18', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '75f10f57-3d7b-4866-b342-17b619115ea9' User entered 'No (N)'	System	08 Aug 2020 22:45:22
	System	08 Aug 2020 22:45:22

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:09:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-08T18:45:20', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '75f10f57-3d7b-4866-b342-17b619115ea9' User entered '08 Aug 2020 18:45'	System	08 Aug 2020 22:45:22
	System	08 Aug 2020 22:45:22

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:09:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 18:00:55

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:09:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 18:00:55

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
Data entry locked.	System	06 Aug 2020 18:00:55
User entered 'Day 4'	System	06 Aug 2020 18:00:55

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:09:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-10T10:10:11', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'b4a9dd53-d3da-4c4f-9626-bb55f4c290cf' User entered 'None (0)'	System	10 Aug 2020 14:10:30
	System	10 Aug 2020 14:10:30

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:09:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-10T10:10:12', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'b4a9dd53-d3da-4c4f-9626-bb55f4c290cf' User entered 'None (0)'	System	10 Aug 2020 14:10:30
	System	10 Aug 2020 14:10:30

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:09:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-10T10:10:15', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'b4a9dd53-d3da-4c4f-9626-bb55f4c290cf' User entered 'None (0)'	System	10 Aug 2020 14:10:30
	System	10 Aug 2020 14:10:30

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:09:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-10T10:10:17', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'b4a9dd53-d3da-4c4f-9626-bb55f4c290cf' User entered 'None (0)'	System	10 Aug 2020 14:10:30
	System	10 Aug 2020 14:10:30

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:09:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-10T10:10:20', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'b4a9dd53-d3da-4c4f-9626-bb55f4c290cf' User entered 'None (0)'	System	10 Aug 2020 14:10:30
	System	10 Aug 2020 14:10:30

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:09:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-10T10:10:22', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'b4a9dd53-d3da-4c4f-9626-bb55f4c290cf' User entered 'None (0)'	System	10 Aug 2020 14:10:30
	System	10 Aug 2020 14:10:30

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:09:28

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 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-10T10:10:27', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'b4a9dd53-d3da-4c4f-9626-bb55f4c290cf' User entered 'No (N)'	System	10 Aug 2020 14:10:30
	System	10 Aug 2020 14:10:30

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:09:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-10T10:10:29', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'b4a9dd53-d3da-4c4f-9626-bb55f4c290cf' User entered '10 Aug 2020 10:10'	System	10 Aug 2020 14:10:30
	System	10 Aug 2020 14:10:30

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:09:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 18:00:55

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:09:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 18:00:55

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
Data entry locked.	System	06 Aug 2020 18:00:55
User entered 'Day 5'	System	06 Aug 2020 18:00:55

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:09:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:09:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:09:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:09:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:09:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:09:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:09:28

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 20:11:24

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:09:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:09:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 18:00:55

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:09:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 18:00:55

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
Data entry locked.	System	06 Aug 2020 18:00:55
User entered 'Day 6'	System	06 Aug 2020 18:00:55

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:09:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-11T18:32:03', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '73e4541a-d658-43d6-9a8f-be7a9588c2a9' User entered 'None (0)'	System	11 Aug 2020 22:32:24
	System	11 Aug 2020 22:32:24

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:09:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-11T18:32:05', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '73e4541a-d658-43d6-9a8f-be7a9588c2a9' User entered 'None (0)'	System	11 Aug 2020 22:32:24
	System	11 Aug 2020 22:32:24

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:09:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-11T18:32:07', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '73e4541a-d658-43d6-9a8f-be7a9588c2a9' User entered 'None (0)'	System	11 Aug 2020 22:32:24
	System	11 Aug 2020 22:32:24

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:09:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-11T18:32:10', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '73e4541a-d658-43d6-9a8f-be7a9588c2a9' User entered 'None (0)'	System	11 Aug 2020 22:32:24
	System	11 Aug 2020 22:32:24

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:09:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-11T18:32:13', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '73e4541a-d658-43d6-9a8f-be7a9588c2a9' User entered 'None (0)'	System	11 Aug 2020 22:32:24
	System	11 Aug 2020 22:32:24

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:09:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-11T18:32:15', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '73e4541a-d658-43d6-9a8f-be7a9588c2a9' User entered 'None (0)'	System	11 Aug 2020 22:32:24
	System	11 Aug 2020 22:32:24

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:09:28

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 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-11T18:32:17', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '73e4541a-d658-43d6-9a8f-be7a9588c2a9' User entered 'No (N)'	System	11 Aug 2020 22:32:24
	System	11 Aug 2020 22:32:24

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:09:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-11T18:32:20', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '73e4541a-d658-43d6-9a8f-be7a9588c2a9' User entered '11 Aug 2020 18:32'	System	11 Aug 2020 22:32:24
	System	11 Aug 2020 22:32:24

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:09:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 18:00:55

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:09:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 18:00:55

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
Data entry locked.	System	06 Aug 2020 18:00:55
User entered 'Day 7'	System	06 Aug 2020 18:00:55

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:09:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-12T12:02:34', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '235e54fd-5746-45da-a725-af08bcae4d4f' User entered 'None (0)'	System	12 Aug 2020 16:03:14
	System	12 Aug 2020 16:03:14

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:09:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-12T12:02:36', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '235e54fd-5746-45da-a725-af08bcae4d4f' User entered 'None (0)'	System	12 Aug 2020 16:03:14
	System	12 Aug 2020 16:03:14

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:09:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-12T12:02:39', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '235e54fd-5746-45da-a725-af08bcae4d4f' User entered 'None (0)'	System	12 Aug 2020 16:03:14
	System	12 Aug 2020 16:03:14

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:09:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-12T12:02:41', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '235e54fd-5746-45da-a725-af08bcae4d4f' User entered 'None (0)'	System	12 Aug 2020 16:03:14
	System	12 Aug 2020 16:03:14

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:09:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-12T12:02:45', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '235e54fd-5746-45da-a725-af08bcae4d4f' User entered 'None (0)'	System	12 Aug 2020 16:03:14
	System	12 Aug 2020 16:03:14

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:09:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-12T12:02:48', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '235e54fd-5746-45da-a725-af08bcae4d4f' User entered 'None (0)'	System	12 Aug 2020 16:03:14
	System	12 Aug 2020 16:03:14

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:09:28

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 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-12T12:03:06', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '235e54fd-5746-45da-a725-af08bcae4d4f' User entered 'No (N)'	System	12 Aug 2020 16:03:14
	System	12 Aug 2020 16:03:14

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:09:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-08-12T12:03:10', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '235e54fd-5746-45da-a725-af08bcae4d4f' User entered '12 Aug 2020 12:03'	System	12 Aug 2020 16:03:14
	System	12 Aug 2020 16:03:14

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:09:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 18:00:55

US3352033

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:09:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 18:00:55

US3352033

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:58:00
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 15:48:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 17:51:23

US3352033

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:58:00
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 15:48:17
User entered '13 Aug 2020'	(b) (4), (b) (6)	13 Aug 2020 17:51:23

US3352033

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:58:00
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 15:48:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	13 Aug 2020 17:51:23

US3352033

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:58:00
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 15:48:17
User entered empty.	(b) (4), (b) (6)	13 Aug 2020 17:51:23

US3352033

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:58:00
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 15:51:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Aug 2020 17:51:28

US3352033

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:58:00
User entered 'I'	System	13 Aug 2020 17:51:28

US3352033

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:58:00
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 15:52:18
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4)	21 Aug 2020 14:44:10

US3352033

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:28

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:58:00
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 15:52:18
User entered '21 Aug 2020'	Yulexis Amestoy (b) (4)	21 Aug 2020 14:44:10

US3352033

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:58:00
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 15:52:18
User entered 'Contact Made (CONTACT MADE)'	Yulexis Amestoy (b) (4)	21 Aug 2020 14:44:10

US3352033

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:58:00
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 15:52:18
User entered empty.	Yulexis Amestoy (b) (4)	21 Aug 2020 14:44:10

US3352033

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:58:00
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 15:52:29
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4)	21 Aug 2020 14:44:17

US3352033

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:58:00
User entered 'I'	System	21 Aug 2020 14:44:17

US3352033

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:21:08
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 15:53:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 20:56:20

US3352033

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:21:08
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 15:53:45
User entered '27 Aug 2020'	(b) (4), (b) (6)	10 Sep 2020 20:56:20

US3352033

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:21:08
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 15:53:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	10 Sep 2020 20:56:20

US3352033

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:21:08
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 15:53:45
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 20:56:20

US3352033

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:21:08
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:12:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 20:56:26

US3352033

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:21:08
User entered 'I'	System	10 Sep 2020 20:56:26

US3352033

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:09:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:17:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 18:18:28

US3352033

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:09:28

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:17:24
User entered '10 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 18:18:28

US3352033

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:09:28

[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 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:17:24
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	11 Sep 2020 18:18:28

US3352033

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:09:28

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered 'VISIT2'	System	11 Sep 2020 18:18:28

US3352033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:28

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	11 Sep 2020 18:19:45

US3352033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:21:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 18:19:45

US3352033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:21:32
User entered '10 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 18:19:45

US3352033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:21:32
User entered '15:35'	(b) (4), (b) (6)	11 Sep 2020 18:19:45

US3352033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered '10 Sep 2020 15:35'	System	11 Sep 2020 18:19:45

US3352033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:21:32
User entered '36.9' C	(b) (4), (b) (6)	11 Sep 2020 18:19:45

US3352033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:21:32
User entered 'Oral (Oral)'	(b) (4), (b) (6)	11 Sep 2020 18:19:45

US3352033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:21:32
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 18:19:45

US3352033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:21:32
User entered '69'	(b) (4), (b) (6)	11 Sep 2020 18:19:45

US3352033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered 'bpm'	System	11 Sep 2020 18:19:45

US3352033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:21:32
User entered '13'	(b) (4), (b) (6)	11 Sep 2020 18:19:45

US3352033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered 'breaths/min'	System	11 Sep 2020 18:19:45

US3352033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:21:32
User entered '135'	(b) (4), (b) (6)	11 Sep 2020 18:19:45

US3352033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered 'mmHg'	System	11 Sep 2020 18:19:45

US3352033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:21:32
User entered '76'	(b) (4), (b) (6)	11 Sep 2020 18:19:45

US3352033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered 'mmHg'	System	11 Sep 2020 18:19:45

US3352033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:28

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	11 Sep 2020 18:19:45

US3352033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:21:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 18:19:45

US3352033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:21:32
User entered '10 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 18:19:45

US3352033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:21:32
User entered '17:03'	(b) (4), (b) (6)	11 Sep 2020 18:19:45

US3352033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered '10 Sep 2020 17:03'	System	11 Sep 2020 18:19:45

US3352033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:21:32
User entered '36.9' C	(b) (4), (b) (6)	11 Sep 2020 18:19:45

US3352033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:21:32
User entered 'Oral (Oral)'	(b) (4), (b) (6)	11 Sep 2020 18:19:45

US3352033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:21:32
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 18:19:45

US3352033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:21:32
User entered '67'	(b) (4), (b) (6)	11 Sep 2020 18:19:45

US3352033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered 'bpm'	System	11 Sep 2020 18:19:45

US3352033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:21:32
User entered '15'	(b) (4), (b) (6)	11 Sep 2020 18:19:45

US3352033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered 'breaths/min'	System	11 Sep 2020 18:19:45

US3352033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:21:32
User entered '123'	(b) (4), (b) (6)	11 Sep 2020 18:19:45

US3352033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered 'mmHg'	System	11 Sep 2020 18:19:45

US3352033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:21:32
User entered '71'	(b) (4), (b) (6)	11 Sep 2020 18:19:45

US3352033

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered 'mmHg'	System	11 Sep 2020 18:19:45

US3352033

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:09:28

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:29:46
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 18:20:03

US3352033

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:09:28

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:29:46
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 18:20:03

US3352033

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:28

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:30:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 20:57:11

US3352033

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:28

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:30:20
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 20:57:11

US3352033

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:30:20
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 20:57:11

US3352033

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:28

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered 'MRNA-1273 OR PLACEBO'	System	10 Sep 2020 20:57:11

US3352033

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:28

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:30:20
User entered '10 Sep 2020'	(b) (4), (b) (6)	10 Sep 2020 20:57:11

US3352033

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:28

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:30:20
User entered '16:33'	(b) (4), (b) (6)	10 Sep 2020 20:57:11

US3352033

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:28

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered '10 Sep 2020 16:33'	System	10 Sep 2020 20:57:11

US3352033

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:28

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:30:20
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	10 Sep 2020 20:57:11

US3352033

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:28

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:30:20
User entered 'ONCE'	System	10 Sep 2020 20:57:11

US3352033

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:28

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered 'INTRAMUSCULAR'	System	10 Sep 2020 20:57:11

US3352033

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:30:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 18:20:24

US3352033

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:28

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:30:47
User entered '10 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 18:20:24

US3352033

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:28

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:30:47
User entered '16:03'	(b) (4), (b) (6)	11 Sep 2020 18:20:24

US3352033

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:28

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered '10 Sep 2020 16:03'	System	11 Sep 2020 18:20:24

US3352033

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:09:28

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:31:41
User entered '10 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 18:20:50

US3352033

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:09:28

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	11 Sep 2020 18:20:50

US3352033

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:09:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:31:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 18:20:50

US3352033

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:09:28

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:31:41
User entered '15:50'	(b) (4), (b) (6)	11 Sep 2020 18:20:50

US3352033

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:09:28

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered '10 Sep 2020 15:50'	System	11 Sep 2020 18:20:50

US3352033

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:09:28

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	11 Sep 2020 18:20:50

US3352033

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:09:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:31:41
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 18:20:50

US3352033

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:09:28

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:31:41
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 18:20:50

US3352033

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:09:28

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered empty.	System	11 Sep 2020 18:20:50

US3352033

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:31:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 18:20:57

US3352033

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:14:58
User entered '1'	System	11 Sep 2020 18:20:57

US3352033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
Data entry locked.	System	10 Sep 2020 20:57:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 20:57:11

US3352033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:09:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-10T17:07:26', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '35c42416-b658-4666-aff1-7d87e3ef9832'	System	10 Sep 2020 21:07:44
User entered 'Yes (Y)'	System	10 Sep 2020 21:07:44

US3352033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:09:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-10T17:07:31', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '35c42416-b658-4666-aff1-7d87e3ef9832' User entered '98.3'	System	10 Sep 2020 21:07:44
	System	10 Sep 2020 21:07:44

US3352033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-10T17:07:36', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '35c42416-b658-4666-aff1-7d87e3ef9832'	System	10 Sep 2020 21:07:44
User entered 'No (N)'	System	10 Sep 2020 21:07:44

US3352033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:09:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-10T17:07:42', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '35c42416-b658-4666-aff1-7d87e3ef9832'	System	10 Sep 2020 21:07:44
User entered '10 Sep 2020 17:07'	System	10 Sep 2020 21:07:44

US3352033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:09:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '10 Sep 2020 16:53'	System	10 Sep 2020 20:57:11

US3352033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:09:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '10 Sep 2020 19:23'	System	10 Sep 2020 20:57:11

US3352033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
Data entry locked.	System	10 Sep 2020 20:57:11
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 20:57:11

US3352033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:09:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-10T23:16:07', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '6698296e-3b35-4093-ad8e-4a6461a70d6f' User entered 'Yes (Y)'	System	11 Sep 2020 03:16:27
	System	11 Sep 2020 03:16:27

US3352033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:09:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-10T23:16:15', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '6698296e-3b35-4093-ad8e-4a6461a70d6f' User entered '98.4'	System	11 Sep 2020 03:16:27
	System	11 Sep 2020 03:16:27

US3352033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-10T23:16:19', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '6698296e-3b35-4093-ad8e-4a6461a70d6f' User entered 'No (N)'	System	11 Sep 2020 03:16:27
	System	11 Sep 2020 03:16:27

US3352033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:09:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-10T23:16:23', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '6698296e-3b35-4093-ad8e-4a6461a70d6f' User entered '10 Sep 2020 23:16'	System	11 Sep 2020 03:16:27
	System	11 Sep 2020 03:16:27

US3352033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:09:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '10 Sep 2020 20:18'	System	10 Sep 2020 20:57:11

US3352033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:09:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 20:57:11

US3352033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
Data entry locked.	System	10 Sep 2020 20:57:11
User entered 'Day 2'	System	10 Sep 2020 20:57:11

US3352033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:09:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-12T04:15:49', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '4966bdb7-c862-4c5e-8b31-0405e02b1934' User entered 'Yes (Y)'	System	13 Sep 2020 10:13:36
	System	13 Sep 2020 10:13:36

US3352033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:09:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-12T04:15:58', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '4966bdb7-c862-4c5e-8b31-0405e02b1934' User entered '98.6'	System	13 Sep 2020 10:13:36
	System	13 Sep 2020 10:13:36

US3352033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-12T04:16:03', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '4966bdb7-c862-4c5e-8b31-0405e02b1934'	System	13 Sep 2020 10:13:36
User entered 'No (N)'	System	13 Sep 2020 10:13:36

US3352033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:09:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-12T04:16:09', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '4966bdb7-c862-4c5e-8b31-0405e02b1934'	System	13 Sep 2020 10:13:36
User entered '12 Sep 2020 04:16'	System	13 Sep 2020 10:13:36

US3352033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:09:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 20:57:11

US3352033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:09:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 20:57:11

US3352033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
Data entry locked.	System	10 Sep 2020 20:57:11
User entered 'Day 3'	System	10 Sep 2020 20:57:11

US3352033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:09:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-13T06:13:39', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '930bd8ca-b944-4f95-8e1e-cee77d6f3f74' User entered 'Yes (Y)'	System	13 Sep 2020 10:14:05
	System	13 Sep 2020 10:14:05

US3352033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:09:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-13T06:13:53', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '930bd8ca-b944-4f95-8e1e-cee77d6f3f74' User entered '98.4'	System	13 Sep 2020 10:14:05
	System	13 Sep 2020 10:14:05

US3352033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-13T06:13:56', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '930bd8ca-b944-4f95-8e1e-cee77d6f3f74'	System	13 Sep 2020 10:14:05
User entered 'No (N)'	System	13 Sep 2020 10:14:05

US3352033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:09:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-13T06:14:01', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '930bd8ca-b944-4f95-8e1e-cee77d6f3f74' User entered '13 Sep 2020 06:14'	System	13 Sep 2020 10:14:05
	System	13 Sep 2020 10:14:05

US3352033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:09:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 20:57:11

US3352033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:09:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 20:57:11

US3352033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
Data entry locked.	System	10 Sep 2020 20:57:11
User entered 'Day 4'	System	10 Sep 2020 20:57:11

US3352033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:09:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-13T12:47:49', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '11ebd2dc-5834-4b37-b35d-ee41762d4f74' User entered 'Yes (Y)'	System	13 Sep 2020 16:48:09
	System	13 Sep 2020 16:48:09

US3352033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:09:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-13T12:47:57', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '11ebd2dc-5834-4b37-b35d-ee41762d4f74' User entered '97.8'	System	13 Sep 2020 16:48:09
	System	13 Sep 2020 16:48:09

US3352033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-13T12:48:00', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '11ebd2dc-5834-4b37-b35d-ee41762d4f74'	System	13 Sep 2020 16:48:09
User entered 'No (N)'	System	13 Sep 2020 16:48:09

US3352033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:09:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-13T12:48:04', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '11ebd2dc-5834-4b37-b35d-ee41762d4f74' User entered '13 Sep 2020 12:48'	System	13 Sep 2020 16:48:09
	System	13 Sep 2020 16:48:09

US3352033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:09:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 20:57:11

US3352033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:09:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 20:57:11

US3352033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
Data entry locked.	System	10 Sep 2020 20:57:11
User entered 'Day 5'	System	10 Sep 2020 20:57:11

US3352033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:09:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24

US3352033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:09:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24

US3352033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24

US3352033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24

US3352033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:09:28

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24

US3352033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:09:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24

US3352033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:09:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 20:57:11

US3352033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:09:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 20:57:11

US3352033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
Data entry locked.	System	10 Sep 2020 20:57:11
User entered 'Day 6'	System	10 Sep 2020 20:57:11

US3352033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:09:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-15T12:01:14', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '3b25e846-2b24-40ed-a290-10c21c68e381' User entered 'Yes (Y)'	System	15 Sep 2020 16:02:45
	System	15 Sep 2020 16:02:45

US3352033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:09:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-15T12:01:21', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '3b25e846-2b24-40ed-a290-10c21c68e381' User entered '98.2'	System	15 Sep 2020 16:02:45
	System	15 Sep 2020 16:02:45

US3352033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-15T12:01:24', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '3b25e846-2b24-40ed-a290-10c21c68e381' User entered 'No (N)'	System	15 Sep 2020 16:02:45
	System	15 Sep 2020 16:02:45

US3352033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:09:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-15T12:01:30', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '3b25e846-2b24-40ed-a290-10c21c68e381' User entered '15 Sep 2020 12:01'	System	15 Sep 2020 16:02:45
	System	15 Sep 2020 16:02:45

US3352033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:09:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 20:57:11

US3352033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:09:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 20:57:11

US3352033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
Data entry locked.	System	10 Sep 2020 20:57:11
User entered 'Day 7'	System	10 Sep 2020 20:57:11

US3352033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:09:28

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-16T12:33:53', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'e8683705-4dab-4126-b94a-e22e450996f3' User entered 'Yes (Y)'	System	16 Sep 2020 16:34:14
	System	16 Sep 2020 16:34:14

US3352033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:09:28

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-16T12:34:04', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'e8683705-4dab-4126-b94a-e22e450996f3' User entered '98.6'	System	16 Sep 2020 16:34:14
	System	16 Sep 2020 16:34:14

US3352033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-16T12:34:08', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'e8683705-4dab-4126-b94a-e22e450996f3'	System	16 Sep 2020 16:34:14
User entered 'No (N)'	System	16 Sep 2020 16:34:14

US3352033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:09:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-16T12:34:11', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'e8683705-4dab-4126-b94a-e22e450996f3'	System	16 Sep 2020 16:34:14
User entered '16 Sep 2020 12:34'	System	16 Sep 2020 16:34:14

US3352033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:09:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 20:57:11

US3352033

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:09:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 20:57:11

US3352033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
Data entry locked.	System	10 Sep 2020 20:57:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 20:57:11

US3352033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:09:28

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 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-10T17:07:48', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '52828bd0-bb1a-4dca-b797-fb2dbae723ba' User entered 'None (1)'	System	10 Sep 2020 21:08:06
	System	10 Sep 2020 21:08:06

US3352033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:09:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-10T17:07:51', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '52828bd0-bb1a-4dca-b797-fb2dbae723ba' User entered 'No (N)'	System	10 Sep 2020 21:08:06
	System	10 Sep 2020 21:08:06

US3352033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-10T17:07:54', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '52828bd0-bb1a-4dca-b797-fb2dbae723ba' User entered 'No (N)'	System	10 Sep 2020 21:08:06
	System	10 Sep 2020 21:08:06

US3352033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:09:28

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 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-10T17:07:56', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '52828bd0-bb1a-4dca-b797-fb2dbae723ba' User entered 'None (1)'	System	10 Sep 2020 21:08:06
	System	10 Sep 2020 21:08:06

US3352033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:09:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-10T17:08:04', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '52828bd0-bb1a-4dca-b797-fb2dbae723ba' User entered '10 Sep 2020 17:08'	System	10 Sep 2020 21:08:06
	System	10 Sep 2020 21:08:06

US3352033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:09:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '10 Sep 2020 16:53'	System	10 Sep 2020 20:57:11

US3352033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:09:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '10 Sep 2020 19:23'	System	10 Sep 2020 20:57:11

US3352033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
Data entry locked.	System	10 Sep 2020 20:57:11
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 20:57:11

US3352033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:09:28

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 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-10T23:16:28', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '0471f0e9-7730-4d95-ad98-02c97bc0bf6e' User entered 'None (1)'	System	11 Sep 2020 03:16:43
	System	11 Sep 2020 03:16:43

US3352033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:09:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-10T23:16:31', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '0471f0e9-7730-4d95-ad98-02c97bc0bf6e' User entered 'No (N)'	System	11 Sep 2020 03:16:43
	System	11 Sep 2020 03:16:43

US3352033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-10T23:16:34', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '0471f0e9-7730-4d95-ad98-02c97bc0bf6e' User entered 'No (N)'	System	11 Sep 2020 03:16:43
	System	11 Sep 2020 03:16:43

US3352033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:09:28

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 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-10T23:16:37', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '0471f0e9-7730-4d95-ad98-02c97bc0bf6e' User entered 'None (1)'	System	11 Sep 2020 03:16:43
	System	11 Sep 2020 03:16:43

US3352033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:09:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-10T23:16:40', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '0471f0e9-7730-4d95-ad98-02c97bc0bf6e' User entered '10 Sep 2020 23:16'	System	11 Sep 2020 03:16:43
	System	11 Sep 2020 03:16:43

US3352033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:09:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '10 Sep 2020 20:18'	System	10 Sep 2020 20:57:11

US3352033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:09:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 20:57:11

US3352033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
Data entry locked.	System	10 Sep 2020 20:57:11
User entered 'Day 2'	System	10 Sep 2020 20:57:11

US3352033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:09:28

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 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-12T04:16:16', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'fb783e3b-24f9-48cc-bdb2-cc54961d124e' User entered 'None (1)'	System	13 Sep 2020 10:13:37
	System	13 Sep 2020 10:13:37

US3352033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:09:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-12T04:16:20', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'fb783e3b-24f9-48cc-bdb2-cc54961d124e' User entered 'No (N)'	System	13 Sep 2020 10:13:37
	System	13 Sep 2020 10:13:37

US3352033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-12T04:16:23', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'fb783e3b-24f9-48cc-bdb2-cc54961d124e' User entered 'No (N)'	System	13 Sep 2020 10:13:37
	System	13 Sep 2020 10:13:37

US3352033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:09:28

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 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-12T04:16:39', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'fb783e3b-24f9-48cc-bdb2-cc54961d124e' User entered 'None (1)'	System	13 Sep 2020 10:13:37
	System	13 Sep 2020 10:13:37

US3352033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:09:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-12T04:16:43', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'fb783e3b-24f9-48cc-bdb2-cc54961d124e' User entered '12 Sep 2020 04:16'	System	13 Sep 2020 10:13:37
	System	13 Sep 2020 10:13:37

US3352033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:09:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 20:57:11

US3352033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:09:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 20:57:11

US3352033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
Data entry locked.	System	10 Sep 2020 20:57:11
User entered 'Day 3'	System	10 Sep 2020 20:57:11

US3352033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:09:28

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 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-13T06:14:06', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '6295eec0-6ccd-4634-a346-11dc409b8e84' User entered 'None (1)'	System	13 Sep 2020 10:14:36
	System	13 Sep 2020 10:14:36

US3352033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:09:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-13T06:14:10', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '6295eec0-6ccd-4634-a346-11dc409b8e84' User entered 'No (N)'	System	13 Sep 2020 10:14:36
	System	13 Sep 2020 10:14:36

US3352033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-13T06:14:25', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '6295eec0-6ccd-4634-a346-11dc409b8e84' User entered 'No (N)'	System	13 Sep 2020 10:14:36
	System	13 Sep 2020 10:14:36

US3352033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:09:28

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 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-13T06:14:29', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '6295eec0-6ccd-4634-a346-11dc409b8e84' User entered 'None (1)'	System	13 Sep 2020 10:14:36
	System	13 Sep 2020 10:14:36

US3352033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:09:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-13T06:14:32', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '6295eec0-6ccd-4634-a346-11dc409b8e84' User entered '13 Sep 2020 06:14'	System	13 Sep 2020 10:14:36
	System	13 Sep 2020 10:14:36

US3352033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:09:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 20:57:11

US3352033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:09:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 20:57:11

US3352033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
Data entry locked.	System	10 Sep 2020 20:57:11
User entered 'Day 4'	System	10 Sep 2020 20:57:11

US3352033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:09:28

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 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-13T12:48:08', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '88c641f9-0140-4cac-9cfc-6e999d6165d3'	System	13 Sep 2020 16:48:21
User entered 'None (1)'	System	13 Sep 2020 16:48:21

US3352033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:09:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-13T12:48:10', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '88c641f9-0140-4cac-9cfc-6e999d6165d3'	System	13 Sep 2020 16:48:21
User entered 'No (N)'	System	13 Sep 2020 16:48:21

US3352033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-13T12:48:13', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '88c641f9-0140-4cac-9cfc-6e999d6165d3' User entered 'No (N)'	System	13 Sep 2020 16:48:21
	System	13 Sep 2020 16:48:21

US3352033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:09:28

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 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-13T12:48:16', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '88c641f9-0140-4cac-9cfc-6e999d6165d3'	System	13 Sep 2020 16:48:21
User entered 'None (1)'	System	13 Sep 2020 16:48:21

US3352033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:09:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-13T12:48:18', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '88c641f9-0140-4cac-9cfc-6e999d6165d3'	System	13 Sep 2020 16:48:21
User entered '13 Sep 2020 12:48'	System	13 Sep 2020 16:48:21

US3352033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:09:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 20:57:11

US3352033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:09:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 20:57:11

US3352033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
Data entry locked.	System	10 Sep 2020 20:57:11
User entered 'Day 5'	System	10 Sep 2020 20:57:11

US3352033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:09:28

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 20:11:24

US3352033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:09:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24

US3352033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:09:28

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 20:11:24

US3352033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24

US3352033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:09:28

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 20:11:24

US3352033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:09:28

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 20:11:24

US3352033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:09:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24

US3352033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:09:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 20:57:11

US3352033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:09:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 20:57:11

US3352033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
Data entry locked.	System	10 Sep 2020 20:57:11
User entered 'Day 6'	System	10 Sep 2020 20:57:11

US3352033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:09:28

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 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-15T12:01:33', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'beb0bdd9-2644-4821-ad68-98d3dc5e034b'	System	15 Sep 2020 16:03:18
User entered 'None (1)'	System	15 Sep 2020 16:03:18

US3352033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:09:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-15T12:01:37', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'beb0bdd9-2644-4821-ad68-98d3dc5e034b' User entered 'No (N)'	System	15 Sep 2020 16:03:18
	System	15 Sep 2020 16:03:18

US3352033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-15T12:01:45', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'beb0bdd9-2644-4821-ad68-98d3dc5e034b' User entered 'No (N)'	System	15 Sep 2020 16:03:18
	System	15 Sep 2020 16:03:18

US3352033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:09:28

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 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-15T12:01:48', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'beb0bdd9-2644-4821-ad68-98d3dc5e034b' User entered 'None (1)'	System	15 Sep 2020 16:03:18
	System	15 Sep 2020 16:03:18

US3352033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:09:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-15T12:01:54', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'beb0bdd9-2644-4821-ad68-98d3dc5e034b' User entered '15 Sep 2020 12:01'	System	15 Sep 2020 16:03:18
	System	15 Sep 2020 16:03:18

US3352033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:09:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 20:57:11

US3352033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:09:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 20:57:11

US3352033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
Data entry locked.	System	10 Sep 2020 20:57:11
User entered 'Day 7'	System	10 Sep 2020 20:57:11

US3352033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:09:28

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 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-16T12:34:15', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '5016efd2-ce42-4c41-810c-c7308d880a9c' User entered 'None (1)'	System	16 Sep 2020 16:34:29
	System	16 Sep 2020 16:34:29

US3352033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:09:28

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-16T12:34:18', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '5016efd2-ce42-4c41-810c-c7308d880a9c' User entered 'No (N)'	System	16 Sep 2020 16:34:29
	System	16 Sep 2020 16:34:29

US3352033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-16T12:34:21', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '5016efd2-ce42-4c41-810c-c7308d880a9c' User entered 'No (N)'	System	16 Sep 2020 16:34:29
	System	16 Sep 2020 16:34:29

US3352033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:09:28

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 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-16T12:34:24', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '5016efd2-ce42-4c41-810c-c7308d880a9c' User entered 'None (1)'	System	16 Sep 2020 16:34:29
	System	16 Sep 2020 16:34:29

US3352033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:09:28

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-16T12:34:27', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '5016efd2-ce42-4c41-810c-c7308d880a9c' User entered '16 Sep 2020 12:34'	System	16 Sep 2020 16:34:29
	System	16 Sep 2020 16:34:29

US3352033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:09:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 20:57:11

US3352033

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:09:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 20:57:11

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
Data entry locked.	System	10 Sep 2020 20:57:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 20:57:11

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:09:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-10T17:08:14', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '337cb953-653d-4144-9f5e-591ef0f89e4f' User entered 'None (0)'	System	10 Sep 2020 21:08:45
	System	10 Sep 2020 21:08:45

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:09:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-10T17:08:20', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '337cb953-653d-4144-9f5e-591ef0f89e4f' User entered 'None (0)'	System	10 Sep 2020 21:08:45
	System	10 Sep 2020 21:08:45

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:09:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-10T17:08:24', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '337cb953-653d-4144-9f5e-591ef0f89e4f' User entered 'None (0)'	System	10 Sep 2020 21:08:45
	System	10 Sep 2020 21:08:45

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:09:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-10T17:08:27', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '337cb953-653d-4144-9f5e-591ef0f89e4f' User entered 'None (0)'	System	10 Sep 2020 21:08:45
	System	10 Sep 2020 21:08:45

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:09:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-10T17:08:30', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '337cb953-653d-4144-9f5e-591ef0f89e4f' User entered 'None (0)'	System	10 Sep 2020 21:08:45
	System	10 Sep 2020 21:08:45

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:09:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-10T17:08:32', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '337cb953-653d-4144-9f5e-591ef0f89e4f' User entered 'None (0)'	System	10 Sep 2020 21:08:45
	System	10 Sep 2020 21:08:45

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:09:28

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 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-10T17:08:35', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '337cb953-653d-4144-9f5e-591ef0f89e4f' User entered 'No (N)'	System	10 Sep 2020 21:08:45
	System	10 Sep 2020 21:08:45

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:09:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-10T17:08:37', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '337cb953-653d-4144-9f5e-591ef0f89e4f' User entered '10 Sep 2020 17:08'	System	10 Sep 2020 21:08:45
	System	10 Sep 2020 21:08:45

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:09:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '10 Sep 2020 16:53'	System	10 Sep 2020 20:57:11

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:09:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '10 Sep 2020 19:23'	System	10 Sep 2020 20:57:11

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
Data entry locked.	System	10 Sep 2020 20:57:11
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 20:57:11

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:09:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-10T23:16:44', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'df1f2f65-d796-4c1a-9e6a-2c91c615fd77' User entered 'None (0)'	System	11 Sep 2020 03:17:02
	System	11 Sep 2020 03:17:02

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:09:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-10T23:16:46', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'df1f2f65-d796-4c1a-9e6a-2c91c615fd77' User entered 'None (0)'	System	11 Sep 2020 03:17:02
	System	11 Sep 2020 03:17:02

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:09:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-10T23:16:48', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'df1f2f65-d796-4c1a-9e6a-2c91c615fd77' User entered 'None (0)'	System	11 Sep 2020 03:17:02
	System	11 Sep 2020 03:17:02

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:09:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-10T23:16:51', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'df1f2f65-d796-4c1a-9e6a-2c91c615fd77' User entered 'None (0)'	System	11 Sep 2020 03:17:02
	System	11 Sep 2020 03:17:02

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:09:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-10T23:16:53', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'df1f2f65-d796-4c1a-9e6a-2c91c615fd77' User entered 'None (0)'	System	11 Sep 2020 03:17:02
	System	11 Sep 2020 03:17:02

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:09:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-10T23:16:54', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'df1f2f65-d796-4c1a-9e6a-2c91c615fd77' User entered 'None (0)'	System	11 Sep 2020 03:17:02
	System	11 Sep 2020 03:17:02

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:09:28

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 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-10T23:16:58', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'df1f2f65-d796-4c1a-9e6a-2c91c615fd77'	System	11 Sep 2020 03:17:02
User entered 'No (N)'	System	11 Sep 2020 03:17:02

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:09:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-10T23:17:00', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'df1f2f65-d796-4c1a-9e6a-2c91c615fd77'	System	11 Sep 2020 03:17:02
User entered '10 Sep 2020 23:17'	System	11 Sep 2020 03:17:02

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:09:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '10 Sep 2020 20:18'	System	10 Sep 2020 20:57:11

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:09:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 20:57:11

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
Data entry locked.	System	10 Sep 2020 20:57:11
User entered 'Day 2'	System	10 Sep 2020 20:57:11

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:09:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-12T04:16:49', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '2f4ca373-1422-4aeb-84b3-fcb5acd9e95e' User entered 'None (0)'	System	13 Sep 2020 10:13:38
	System	13 Sep 2020 10:13:38

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:09:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-12T04:16:51', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '2f4ca373-1422-4aeb-84b3-fcb5acd9e95e' User entered 'None (0)'	System	13 Sep 2020 10:13:38
	System	13 Sep 2020 10:13:38

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:09:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-12T04:16:52', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '2f4ca373-1422-4aeb-84b3-fcb5acd9e95e' User entered 'None (0)'	System	13 Sep 2020 10:13:38
	System	13 Sep 2020 10:13:38

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:09:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-12T04:16:54', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '2f4ca373-1422-4aeb-84b3-fcb5acd9e95e' User entered 'None (0)'	System	13 Sep 2020 10:13:38
	System	13 Sep 2020 10:13:38

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:09:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-12T04:16:56', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '2f4ca373-1422-4aeb-84b3-fcb5acd9e95e' User entered 'None (0)'	System	13 Sep 2020 10:13:38
	System	13 Sep 2020 10:13:38

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:09:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-12T04:16:59', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '2f4ca373-1422-4aeb-84b3-fcb5acd9e95e' User entered 'None (0)'	System	13 Sep 2020 10:13:38
	System	13 Sep 2020 10:13:38

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:09:28

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 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-12T04:17:02', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '2f4ca373-1422-4aeb-84b3-fcb5acd9e95e' User entered 'No (N)'	System	13 Sep 2020 10:13:38
	System	13 Sep 2020 10:13:38

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:09:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-12T04:17:05', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '2f4ca373-1422-4aeb-84b3-fcb5acd9e95e' User entered '12 Sep 2020 04:17'	System	13 Sep 2020 10:13:38
	System	13 Sep 2020 10:13:38

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:09:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 20:57:11

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:09:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 20:57:11

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
Data entry locked.	System	10 Sep 2020 20:57:11
User entered 'Day 3'	System	10 Sep 2020 20:57:11

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:09:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-13T06:14:36', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '95e7dfa9-91cf-404f-af51-1d44a3c5428a' User entered 'None (0)'	System	13 Sep 2020 10:15:05
	System	13 Sep 2020 10:15:05

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:09:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-13T06:14:39', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '95e7dfa9-91cf-404f-af51-1d44a3c5428a' User entered 'None (0)'	System	13 Sep 2020 10:15:05
	System	13 Sep 2020 10:15:05

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:09:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-13T06:14:42', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '95e7dfa9-91cf-404f-af51-1d44a3c5428a' User entered 'None (0)'	System	13 Sep 2020 10:15:05
	System	13 Sep 2020 10:15:05

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:09:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-13T06:14:45', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '95e7dfa9-91cf-404f-af51-1d44a3c5428a' User entered 'None (0)'	System	13 Sep 2020 10:15:05
	System	13 Sep 2020 10:15:05

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:09:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-13T06:14:48', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '95e7dfa9-91cf-404f-af51-1d44a3c5428a' User entered 'None (0)'	System	13 Sep 2020 10:15:05
	System	13 Sep 2020 10:15:05

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:09:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-13T06:14:50', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '95e7dfa9-91cf-404f-af51-1d44a3c5428a' User entered 'None (0)'	System	13 Sep 2020 10:15:05
	System	13 Sep 2020 10:15:05

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:09:28

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 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-13T06:14:56', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '95e7dfa9-91cf-404f-af51-1d44a3c5428a' User entered 'No (N)'	System	13 Sep 2020 10:15:05
	System	13 Sep 2020 10:15:05

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:09:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-13T06:14:59', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '95e7dfa9-91cf-404f-af51-1d44a3c5428a' User entered '13 Sep 2020 06:14'	System	13 Sep 2020 10:15:05
	System	13 Sep 2020 10:15:05

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:09:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 20:57:11

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:09:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 20:57:11

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
Data entry locked.	System	10 Sep 2020 20:57:11
User entered 'Day 4'	System	10 Sep 2020 20:57:11

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:09:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-13T12:49:25', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'a4f8345c-c3e5-47a3-adbe-712ad3eb0baa' User entered 'None (0)'	System	13 Sep 2020 16:49:45
	System	13 Sep 2020 16:49:45

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:09:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-13T12:49:26', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'a4f8345c-c3e5-47a3-adbe-712ad3eb0baa' User entered 'None (0)'	System	13 Sep 2020 16:49:45
	System	13 Sep 2020 16:49:45

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:09:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-13T12:49:29', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'a4f8345c-c3e5-47a3-adbe-712ad3eb0baa' User entered 'None (0)'	System	13 Sep 2020 16:49:45
	System	13 Sep 2020 16:49:45

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:09:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-13T12:49:31', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'a4f8345c-c3e5-47a3-adbe-712ad3eb0baa' User entered 'None (0)'	System	13 Sep 2020 16:49:45
	System	13 Sep 2020 16:49:45

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:09:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-13T12:49:34', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'a4f8345c-c3e5-47a3-adbe-712ad3eb0baa' User entered 'None (0)'	System	13 Sep 2020 16:49:45
	System	13 Sep 2020 16:49:45

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:09:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-13T12:49:36', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'a4f8345c-c3e5-47a3-adbe-712ad3eb0baa' User entered 'None (0)'	System	13 Sep 2020 16:49:45
	System	13 Sep 2020 16:49:45

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:09:28

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 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-13T12:49:41', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'a4f8345c-c3e5-47a3-adbe-712ad3eb0baa' User entered 'No (N)'	System	13 Sep 2020 16:49:45
	System	13 Sep 2020 16:49:45

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:09:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-13T12:49:43', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'a4f8345c-c3e5-47a3-adbe-712ad3eb0baa' User entered '13 Sep 2020 12:49'	System	13 Sep 2020 16:49:45
	System	13 Sep 2020 16:49:45

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:09:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 20:57:11

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:09:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 20:57:11

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
Data entry locked.	System	10 Sep 2020 20:57:11
User entered 'Day 5'	System	10 Sep 2020 20:57:11

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:09:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:09:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:09:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:09:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:09:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:09:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:09:28

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 20:11:24

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:09:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:09:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 20:57:11

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:09:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 20:57:11

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
Data entry locked.	System	10 Sep 2020 20:57:11
User entered 'Day 6'	System	10 Sep 2020 20:57:11

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:09:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-15T12:02:01', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '12dda712-feeb-482c-9ea7-fa3148b27e77'	System	15 Sep 2020 16:03:45
User entered 'None (0)'	System	15 Sep 2020 16:03:45

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:09:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-15T12:02:03', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '12dda712-feeb-482c-9ea7-fa3148b27e77' User entered 'None (0)'	System	15 Sep 2020 16:03:45
	System	15 Sep 2020 16:03:45

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:09:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-15T12:02:05', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '12dda712-feeb-482c-9ea7-fa3148b27e77' User entered 'None (0)'	System	15 Sep 2020 16:03:45
	System	15 Sep 2020 16:03:45

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:09:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-15T12:02:08', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '12dda712-feeb-482c-9ea7-fa3148b27e77' User entered 'None (0)'	System	15 Sep 2020 16:03:45
	System	15 Sep 2020 16:03:45

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:09:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-15T12:02:12', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '12dda712-feeb-482c-9ea7-fa3148b27e77' User entered 'None (0)'	System	15 Sep 2020 16:03:45
	System	15 Sep 2020 16:03:45

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:09:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-15T12:02:14', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '12dda712-feeb-482c-9ea7-fa3148b27e77' User entered 'None (0)'	System	15 Sep 2020 16:03:45
	System	15 Sep 2020 16:03:45

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:09:28

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 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-15T12:02:17', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '12dda712-feeb-482c-9ea7-fa3148b27e77'	System	15 Sep 2020 16:03:45
User entered 'No (N)'	System	15 Sep 2020 16:03:45

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:09:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-15T12:02:21', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '12dda712-feeb-482c-9ea7-fa3148b27e77' User entered '15 Sep 2020 12:02'	System	15 Sep 2020 16:03:45
	System	15 Sep 2020 16:03:45

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:09:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 20:57:11

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:09:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 20:57:11

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
Data entry locked.	System	10 Sep 2020 20:57:11
User entered 'Day 7'	System	10 Sep 2020 20:57:11

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:09:28

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-16T12:34:30', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '91d04cf1-57a6-480c-a86f-109ea7f77152'	System	16 Sep 2020 16:34:48
User entered 'None (0)'	System	16 Sep 2020 16:34:48

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:09:28

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-16T12:34:32', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '91d04cf1-57a6-480c-a86f-109ea7f77152' User entered 'None (0)'	System	16 Sep 2020 16:34:48
	System	16 Sep 2020 16:34:48

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:09:28

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-16T12:34:34', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '91d04cf1-57a6-480c-a86f-109ea7f77152' User entered 'None (0)'	System	16 Sep 2020 16:34:48
	System	16 Sep 2020 16:34:48

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:09:28

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-16T12:34:36', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '91d04cf1-57a6-480c-a86f-109ea7f77152'	System	16 Sep 2020 16:34:48
User entered 'None (0)'	System	16 Sep 2020 16:34:48

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:09:28

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-16T12:34:38', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '91d04cf1-57a6-480c-a86f-109ea7f77152' User entered 'None (0)'	System	16 Sep 2020 16:34:48
	System	16 Sep 2020 16:34:48

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:09:28

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-16T12:34:40', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '91d04cf1-57a6-480c-a86f-109ea7f77152'	System	16 Sep 2020 16:34:48
User entered 'None (0)'	System	16 Sep 2020 16:34:48

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:09:28

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 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-16T12:34:44', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '91d04cf1-57a6-480c-a86f-109ea7f77152'	System	16 Sep 2020 16:34:48
User entered 'No (N)'	System	16 Sep 2020 16:34:48

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:09:28

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-09-16T12:34:46', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '91d04cf1-57a6-480c-a86f-109ea7f77152'	System	16 Sep 2020 16:34:48
User entered '16 Sep 2020 12:34'	System	16 Sep 2020 16:34:48

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:09:28

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 20:57:11

US3352033

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:09:28

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 20:57:11

US3352033

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:52
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:50:23
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4)	18 Sep 2020 15:35:10

US3352033

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:28

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:52
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:50:23
User entered '18 Sep 2020'	Yulexis Amestoy (b) (4)	18 Sep 2020 15:35:10

US3352033

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:52
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:50:23
User entered 'Contact Made (CONTACT MADE)'	Yulexis Amestoy (b) (4)	18 Sep 2020 15:35:10

US3352033

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:52
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:50:23
User entered empty.	Yulexis Amestoy (b) (4)	18 Sep 2020 15:35:10

US3352033

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:52
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:50:29
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4)	18 Sep 2020 15:35:16

US3352033

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:52
User entered 'I'	System	18 Sep 2020 15:35:16

US3352033

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:52
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:50:37
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4)	25 Sep 2020 14:14:43

US3352033

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:28

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:52
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:50:37
User entered '25 Sep 2020'	Yulexis Amestoy (b) (4)	25 Sep 2020 14:14:43

US3352033

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:52
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:50:37
User entered 'Contact Made (CONTACT MADE)'	Yulexis Amestoy (b) (4)	25 Sep 2020 14:14:43

US3352033

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:52
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:50:37
User entered empty.	Yulexis Amestoy (b) (4)	25 Sep 2020 14:14:43

US3352033

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:52
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:50:43
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4)	25 Sep 2020 14:14:49

US3352033

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:52
User entered 'I'	System	25 Sep 2020 14:14:49

US3352033

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:52
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:39:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 14:45:45

US3352033

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:52
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:39:20
User entered '1 Oct 2020'	(b) (4), (b) (6)	01 Oct 2020 14:45:45

US3352033

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:52
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:39:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	01 Oct 2020 14:45:45

US3352033

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:52
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:39:20
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 14:45:45

US3352033

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:52
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:39:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 14:48:20

US3352033

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:52
User entered 'I'	System	01 Oct 2020 14:48:20

US3352033

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:09:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:52
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:29:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 20:47:12

US3352033

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:09:28

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:52
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:29:07
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 08:14:24
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 16:46:09
User entered '08 Oct 2020' reason for change: Data Entry Error	Matthew Muniz (b) (4)	05 Nov 2020 16:46:03
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 08:49:09
User entered '8 Oct 2020'	(b) (4), (b) (6)	08 Oct 2020 20:47:12

US3352033

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:09:28

[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 11:02:52
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:29:07
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	08 Oct 2020 20:47:12

US3352033

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:09:28

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:52
User entered 'VISIT3'	System	08 Oct 2020 20:47:12

US3352033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:52
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:29:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 20:47:52

US3352033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:52
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:29:25
User entered '08 Oct 2020' reason for change: Data Entry Error	Matthew Muniz (b) (4)	05 Nov 2020 16:46:17
User entered '8 Oct 2020'	(b) (4), (b) (6)	08 Oct 2020 20:47:52

US3352033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:52
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:29:25
User entered '14:49'	(b) (4), (b) (6)	08 Oct 2020 20:47:52

US3352033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:52
User entered '08 Oct 2020 14:49'	System	05 Nov 2020 16:46:17
User entered '8 Oct 2020 14:49'	System	08 Oct 2020 20:47:52

US3352033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:52
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:29:25
User entered '36.8' C	(b) (4), (b) (6)	08 Oct 2020 20:47:52

US3352033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:52
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:29:25
User entered 'Oral (Oral)'	(b) (4), (b) (6)	08 Oct 2020 20:47:52

US3352033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:52
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:29:25
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 20:47:52

US3352033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:52
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:29:25
User entered '86'	(b) (4), (b) (6)	08 Oct 2020 20:47:52

US3352033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:52
User entered 'bpm'	System	08 Oct 2020 20:47:52

US3352033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:52
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:29:25
User entered '15'	(b) (4), (b) (6)	08 Oct 2020 20:47:52

US3352033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:52
User entered 'breaths/min'	System	08 Oct 2020 20:47:52

US3352033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:52
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:29:25
User entered '140'	(b) (4), (b) (6)	08 Oct 2020 20:47:52

US3352033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:52
User entered 'mmHg'	System	08 Oct 2020 20:47:52

US3352033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:52
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:29:25
User entered '88'	(b) (4), (b) (6)	08 Oct 2020 20:47:52

US3352033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:52
User entered 'mmHg'	System	08 Oct 2020 20:47:52

US3352033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:28

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	29 Apr 2021 11:02:52

US3352033

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:28

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	29 Apr 2021 11:02:52

US3352033

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:09:28

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:52
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:29:38
User entered 'No (N)'	(b) (4), (b) (6)	08 Oct 2020 20:48:00

US3352033

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:09:28

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:52
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:29:38
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 20:48:00

US3352033

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:52
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:30:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 20:48:14

US3352033

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:28

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:52
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:30:35
User entered '08 Oct 2020' reason for change: Data Entry Error	Matthew Muniz (b) (4)	05 Nov 2020 16:46:23
User entered '8 Oct 2020'	(b) (4), (b) (6)	08 Oct 2020 20:48:14

US3352033

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:28

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:52
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:30:35
User entered '14:52'	(b) (4), (b) (6)	08 Oct 2020 20:48:14

US3352033

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:28

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:52
User entered '08 Oct 2020 14:52'	System	05 Nov 2020 16:46:23
User entered '8 Oct 2020 14:52'	System	08 Oct 2020 20:48:14

US3352033

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:52
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 17:30:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 20:48:18

US3352033

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:02:52
User entered '1'	System	08 Oct 2020 20:48:18

US3352033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
Data entry locked.	System	06 Aug 2020 18:00:55
User entered 'Day 64'	System	06 Aug 2020 18:00:55

US3352033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[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 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-10-06T08:03:11', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '25a99a4e-e204-49a4-ad4a-06611138c0b4' User entered 'No (N)'	System	06 Oct 2020 12:03:23
	System	06 Oct 2020 12:03:23

US3352033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

Have you been exposed to someone with 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 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-10-06T08:03:15', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '25a99a4e-e204-49a4-ad4a-06611138c0b4' User entered 'No (N)'	System	06 Oct 2020 12:03:23
	System	06 Oct 2020 12:03:23

US3352033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-10-06T08:03:21', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '25a99a4e-e204-49a4-ad4a-06611138c0b4' User entered '06 Oct 2020 08:03:21'	System	06 Oct 2020 12:03:23
	System	06 Oct 2020 12:03:23

US3352033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
Data entry locked.	System	06 Aug 2020 18:00:55
User entered '06 Oct 2020 00:01'	System	06 Aug 2020 18:00:55

US3352033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
Data entry locked.	System	06 Aug 2020 18:00:55
User entered '10 Oct 2020 23:59'	System	06 Aug 2020 18:00:55

US3352033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
Data entry locked.	System	06 Aug 2020 18:00:55
User entered 'Day 71'	System	06 Aug 2020 18:00:55

US3352033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[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 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-10-15T15:02:21', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '2bed52a0-ee67-4174-9a43-cf312b43ee96'	System	15 Oct 2020 19:02:38
User entered 'No (N)'	System	15 Oct 2020 19:02:38

US3352033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

Have you been exposed to someone with 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 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-10-15T15:02:24', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '2bed52a0-ee67-4174-9a43-cf312b43ee96'	System	15 Oct 2020 19:02:38
User entered 'No (N)'	System	15 Oct 2020 19:02:38

US3352033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-10-15T15:02:34', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '2bed52a0-ee67-4174-9a43-cf312b43ee96' User entered '15 Oct 2020 15:02:34'	System	15 Oct 2020 19:02:38
	System	15 Oct 2020 19:02:38

US3352033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
Data entry locked.	System	06 Aug 2020 18:00:55
User entered '13 Oct 2020 00:01'	System	06 Aug 2020 18:00:55

US3352033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
Data entry locked.	System	06 Aug 2020 18:00:55
User entered '17 Oct 2020 23:59'	System	06 Aug 2020 18:00:55

US3352033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
Data entry locked.	System	06 Aug 2020 18:00:55
User entered 'Day 78'	System	06 Aug 2020 18:00:55

US3352033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[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 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-10-22T12:58:00', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'd0767066-8bea-439c-b6c3-83a47b82c559'	System	22 Oct 2020 16:58:13
User entered 'No (N)'	System	22 Oct 2020 16:58:13

US3352033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

Have you been exposed to someone with 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 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-10-22T12:58:04', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'd0767066-8bea-439c-b6c3-83a47b82c559'	System	22 Oct 2020 16:58:13
User entered 'No (N)'	System	22 Oct 2020 16:58:13

US3352033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-10-22T12:58:12', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'd0767066-8bea-439c-b6c3-83a47b82c559' User entered '22 Oct 2020 12:58:12'	System	22 Oct 2020 16:58:13
	System	22 Oct 2020 16:58:13

US3352033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
Data entry locked.	System	06 Aug 2020 18:00:55
User entered '20 Oct 2020 00:01'	System	06 Aug 2020 18:00:55

US3352033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
Data entry locked.	System	06 Aug 2020 18:00:55
User entered '24 Oct 2020 23:59'	System	06 Aug 2020 18:00:55

US3352033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
Data entry locked.	System	06 Aug 2020 18:00:55
User entered 'Day 92'	System	06 Aug 2020 18:00:55

US3352033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[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 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-11-03T07:06:47', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '8a2f4890-60a6-4cf3-a639-49404a7d8549'	System	03 Nov 2020 12:06:59
User entered 'No (N)'	System	03 Nov 2020 12:06:59

US3352033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

Have you been exposed to someone with 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 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-11-03T07:06:52', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '8a2f4890-60a6-4cf3-a639-49404a7d8549'	System	03 Nov 2020 12:06:59
User entered 'No (N)'	System	03 Nov 2020 12:06:59

US3352033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-11-03T07:06:55', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '8a2f4890-60a6-4cf3-a639-49404a7d8549' User entered '03 Nov 2020 07:06:55'	System	03 Nov 2020 12:06:59
	System	03 Nov 2020 12:06:59

US3352033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
Data entry locked.	System	06 Aug 2020 18:00:55
User entered '03 Nov 2020 00:01'	System	06 Aug 2020 18:00:55

US3352033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
Data entry locked.	System	06 Aug 2020 18:00:55
User entered '07 Nov 2020 23:59'	System	06 Aug 2020 18:00:55

US3352033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
Data entry locked.	System	06 Aug 2020 18:00:55
User entered 'Day 99'	System	06 Aug 2020 18:00:55

US3352033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[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 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-11-11T10:11:31', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '6fbdecf9-e5e8-4620-8420-3210e13d8582' User entered 'No (N)'	System	11 Nov 2020 15:11:44
	System	11 Nov 2020 15:11:44

US3352033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

Have you been exposed to someone with 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 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-11-11T10:11:35', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '6fbdecf9-e5e8-4620-8420-3210e13d8582'	System	11 Nov 2020 15:11:44
User entered 'No (N)'	System	11 Nov 2020 15:11:44

US3352033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-11-11T10:11:41', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '6fbdecf9-e5e8-4620-8420-3210e13d8582' User entered '11 Nov 2020 10:11:41'	System	11 Nov 2020 15:11:44
	System	11 Nov 2020 15:11:44

US3352033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
Data entry locked.	System	06 Aug 2020 18:00:55
User entered '10 Nov 2020 00:01'	System	06 Aug 2020 18:00:55

US3352033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:11:24
Data entry locked.	System	06 Aug 2020 18:00:55
User entered '14 Nov 2020 23:59'	System	06 Aug 2020 18:00:55

US3352033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:07:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:41:46
Data entry locked.	System	06 Aug 2020 18:00:55
User entered 'Day 106'	System	06 Aug 2020 18:00:55

US3352033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:07:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:41:46

US3352033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:07:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:41:46

US3352033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:07:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:41:46

US3352033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:07:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:41:46

US3352033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:07:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:41:46

US3352033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:07:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:41:46

US3352033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:07:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:41:46

US3352033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:07:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:41:46

US3352033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:07:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:41:46

US3352033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:07:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:41:46

US3352033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:07:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:41:46

US3352033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:07:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:41:46

US3352033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:07:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:41:46

US3352033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:07:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:41:46

US3352033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:07:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:41:46

US3352033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:07:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:41:46

US3352033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:07:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:41:46

US3352033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:07:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:41:46

US3352033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:07:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:41:46

US3352033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:07:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:41:46

US3352033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:07:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:41:46

US3352033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:07:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:41:46

US3352033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:07:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:41:46

US3352033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:07:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:41:46

US3352033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:07:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:41:46

US3352033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:07:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:41:46
Data entry locked.	System	06 Aug 2020 18:00:55
User entered '17 Nov 2020 00:01'	System	06 Aug 2020 18:00:55

US3352033

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:07:53
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:41:46
Data entry locked.	System	06 Aug 2020 18:00:55
User entered '21 Nov 2020 23:59'	System	06 Aug 2020 18:00:55

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[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 (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-11-21T13:59:04', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '5d08b111-3bd5-4c4c-8d31-01d362150c7d'	System	21 Nov 2020 18:59:20
User entered 'No (N)'	System	21 Nov 2020 18:59:20

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

Have you been exposed to someone with 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 (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-11-21T13:59:12', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '5d08b111-3bd5-4c4c-8d31-01d362150c7d'	System	21 Nov 2020 18:59:20
User entered 'No (N)'	System	21 Nov 2020 18:59:20

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-11-21T13:59:17', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '5d08b111-3bd5-4c4c-8d31-01d362150c7d' User entered '21 Nov 2020 13:59:17'	System	21 Nov 2020 18:59:20
	System	21 Nov 2020 18:59:20

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[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 (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-11-30T12:25:01', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '82b6c65c-2664-4540-813a-763e1930b285' User entered 'No (N)'	System	30 Nov 2020 17:25:20
	System	30 Nov 2020 17:25:20

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

Have you been exposed to someone with 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 (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-11-30T12:25:05', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '82b6c65c-2664-4540-813a-763e1930b285'	System	30 Nov 2020 17:25:20
User entered 'No (N)'	System	30 Nov 2020 17:25:20

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-11-30T12:25:18', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '82b6c65c-2664-4540-813a-763e1930b285'	System	30 Nov 2020 17:25:20
User entered '30 Nov 2020 12:25:18'	System	30 Nov 2020 17:25:20

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[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 (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-12-05T08:02:34', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '97c8125b-f876-420e-a564-fbe2135183f2' User entered 'No (N)'	System	05 Dec 2020 13:02:43
	System	05 Dec 2020 13:02:43

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

Have you been exposed to someone with 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 (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-12-05T08:02:38', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '97c8125b-f876-420e-a564-fbe2135183f2' User entered 'No (N)'	System	05 Dec 2020 13:02:43
	System	05 Dec 2020 13:02:43

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-12-05T08:02:41', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '97c8125b-f876-420e-a564-fbe2135183f2' User entered '05 Dec 2020 08:02:41'	System	05 Dec 2020 13:02:43
	System	05 Dec 2020 13:02:43

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[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 (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-12-12T07:08:44', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'd0a59880-5841-4ee5-be4f-4e347464e43b' User entered 'No (N)'	System	12 Dec 2020 12:08:55
	System	12 Dec 2020 12:08:55

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

Have you been exposed to someone with 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 (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-12-12T07:08:47', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'd0a59880-5841-4ee5-be4f-4e347464e43b' User entered 'No (N)'	System	12 Dec 2020 12:08:55
	System	12 Dec 2020 12:08:55

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-12-12T07:08:49', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'd0a59880-5841-4ee5-be4f-4e347464e43b' User entered '12 Dec 2020 07:08:49'	System	12 Dec 2020 12:08:55
	System	12 Dec 2020 12:08:55

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[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 (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-12-21T10:25:05', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'db7b1da3-e89f-4607-9082-5179bb84e6c6' User entered 'No (N)'	System	21 Dec 2020 15:25:31
	System	21 Dec 2020 15:25:31

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

Have you been exposed to someone with 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 (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-12-21T10:25:08', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'db7b1da3-e89f-4607-9082-5179bb84e6c6'	System	21 Dec 2020 15:25:31
User entered 'No (N)'	System	21 Dec 2020 15:25:31

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-12-21T10:25:27', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'db7b1da3-e89f-4607-9082-5179bb84e6c6' User entered '21 Dec 2020 10:25:27'	System	21 Dec 2020 15:25:31
	System	21 Dec 2020 15:25:31

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[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 (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-12-26T08:31:29', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'ba13838b-fc05-4e37-9ff5-fc5c3b3955da' User entered 'No (N)'	System	26 Dec 2020 13:31:38
	System	26 Dec 2020 13:31:38

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

Have you been exposed to someone with 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 (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-12-26T08:31:32', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'ba13838b-fc05-4e37-9ff5-fc5c3b3955da' User entered 'No (N)'	System	26 Dec 2020 13:31:38
	System	26 Dec 2020 13:31:38

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2020-12-26T08:31:35', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'ba13838b-fc05-4e37-9ff5-fc5c3b3955da' User entered '26 Dec 2020 08:31:35'	System	26 Dec 2020 13:31:38
	System	26 Dec 2020 13:31:38

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

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 (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2021-01-02T08:18:53', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '35e32400-12f8-4f91-bfb2-ff9e0117f206' User entered 'No (N)'	System	02 Jan 2021 13:19:22
	System	02 Jan 2021 13:19:22

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

Have you been exposed to someone with 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 (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2021-01-02T08:19:01', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '35e32400-12f8-4f91-bfb2-ff9e0117f206'	System	02 Jan 2021 13:19:22
User entered 'No (N)'	System	02 Jan 2021 13:19:22

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2021-01-02T08:19:20', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '35e32400-12f8-4f91-bfb2-ff9e0117f206' User entered '02 Jan 2021 08:19:20'	System	02 Jan 2021 13:19:22
	System	02 Jan 2021 13:19:22

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[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 (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2021-01-09T08:01:30', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '095f245e-46ed-4069-8c63-15bc2aa81ff4'	System	09 Jan 2021 13:01:39
User entered 'No (N)'	System	09 Jan 2021 13:01:39

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

Have you been exposed to someone with 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 (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2021-01-09T08:01:33', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '095f245e-46ed-4069-8c63-15bc2aa81ff4'	System	09 Jan 2021 13:01:39
User entered 'No (N)'	System	09 Jan 2021 13:01:39

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2021-01-09T08:01:37', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '095f245e-46ed-4069-8c63-15bc2aa81ff4' User entered '09 Jan 2021 08:01:37'	System	09 Jan 2021 13:01:39
	System	09 Jan 2021 13:01:39

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[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 (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2021-01-18T14:37:31', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '2652124c-8d37-4886-8dbb-db6df6f4178f' User entered 'No (N)'	System	18 Jan 2021 19:37:42
	System	18 Jan 2021 19:37:42

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

Have you been exposed to someone with 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 (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2021-01-18T14:37:36', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '2652124c-8d37-4886-8dbb-db6df6f4178f' User entered 'No (N)'	System	18 Jan 2021 19:37:42
	System	18 Jan 2021 19:37:42

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2021-01-18T14:37:39', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '2652124c-8d37-4886-8dbb-db6df6f4178f' User entered '18 Jan 2021 14:37:39'	System	18 Jan 2021 19:37:42
	System	18 Jan 2021 19:37:42

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[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 (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2021-01-25T12:40:42', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '2008b770-2535-43c3-ba15-e731caead7c' User entered 'No (N)'	System	25 Jan 2021 17:40:54
	System	25 Jan 2021 17:40:54

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

Have you been exposed to someone with 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 (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2021-01-25T12:40:46', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '2008b770-2535-43c3-ba15-e731caead7c' User entered 'No (N)'	System	25 Jan 2021 17:40:54
	System	25 Jan 2021 17:40:54

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2021-01-25T12:40:51', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '2008b770-2535-43c3-ba15-e731caae7c' User entered '25 Jan 2021 12:40:51'	System	25 Jan 2021 17:40:54
	System	25 Jan 2021 17:40:54

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[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 (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2021-02-02T10:45:25', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '0a062e45-e8f6-44b5-9922-79834ce882ac' User entered 'No (N)'	System	02 Feb 2021 15:45:43

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

Have you been exposed to someone with 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 (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2021-02-02T10:45:29', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '0a062e45-e8f6-44b5-9922-79834ce882ac' User entered 'No (N)'	System	02 Feb 2021 15:45:43

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2021-02-02T10:45:39', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '0a062e45-e8f6-44b5-9922-79834ce882ac' User entered '02 Feb 2021 10:45:39'	System	02 Feb 2021 15:45:43
	System	02 Feb 2021 15:45:43

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[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 (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2021-02-10T11:59:12', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '90df1f5f-2bff-4d5e-8c52-4837e6be8f8b' User entered 'No (N)'	System	10 Feb 2021 16:59:23
	System	10 Feb 2021 16:59:23

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

Have you been exposed to someone with 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 (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2021-02-10T11:59:17', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '90df1f5f-2bff-4d5e-8c52-4837e6be8f8b' User entered 'No (N)'	System	10 Feb 2021 16:59:23

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2021-02-10T11:59:20', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '90df1f5f-2bff-4d5e-8c52-4837e6be8f8b' User entered '10 Feb 2021 11:59:20'	System	10 Feb 2021 16:59:23
	System	10 Feb 2021 16:59:23

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[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 (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2021-02-17T17:23:49', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'c1d851b7-4f45-41b8-a7ae-26817a5f8100'	System	17 Feb 2021 22:23:58
User entered 'No (N)'	System	17 Feb 2021 22:23:58

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

Have you been exposed to someone with 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 (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2021-02-17T17:23:54', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'c1d851b7-4f45-41b8-a7ae-26817a5f8100'	System	17 Feb 2021 22:23:58
User entered 'No (N)'	System	17 Feb 2021 22:23:58

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2021-02-17T17:23:56', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'c1d851b7-4f45-41b8-a7ae-26817a5f8100'	System	17 Feb 2021 22:23:58
User entered '17 Feb 2021 17:23:56'	System	17 Feb 2021 22:23:58

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[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 (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2021-02-22T12:24:49', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '20690f4b-77f7-4ba2-96d2-602320dd0a30' User entered 'No (N)'	System	22 Feb 2021 17:24:57
	System	22 Feb 2021 17:24:57

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

Have you been exposed to someone with 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 (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2021-02-22T12:24:52', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '20690f4b-77f7-4ba2-96d2-602320dd0a30' User entered 'No (N)'	System	22 Feb 2021 17:24:57
	System	22 Feb 2021 17:24:57

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2021-02-22T12:24:55', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '20690f4b-77f7-4ba2-96d2-602320dd0a30' User entered '22 Feb 2021 12:24:55'	System	22 Feb 2021 17:24:57
	System	22 Feb 2021 17:24:57

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[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 (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2021-03-01T12:08:03-05:00', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'ce38ec39-5522-460f-b6fb-13b975ace4e0'	System	01 Mar 2021 17:20:44
User entered 'No (N)'	System	01 Mar 2021 17:20:44

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

Have you been exposed to someone with 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 (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2021-03-01T12:07:58-05:00', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'ce38ec39-5522-460f-b6fb-13b975ace4e0'	System	01 Mar 2021 17:20:44
User entered 'No (N)'	System	01 Mar 2021 17:20:44

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2021-03-01T12:08:07-05:00', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'ce38ec39-5522-460f-b6fb-13b975ace4e0' User entered '01 Mar 2021 12:08:07'	System	01 Mar 2021 17:20:44
	System	01 Mar 2021 17:20:44

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[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 (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2021-03-06T09:12:12-05:00', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '8377730b-9163-4234-90ae-5461d792fa11'	System	06 Mar 2021 14:12:20
User entered 'No (N)'	System	06 Mar 2021 14:12:20

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

Have you been exposed to someone with 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 (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2021-03-06T09:12:04-05:00', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '8377730b-9163-4234-90ae-5461d792fa11'	System	06 Mar 2021 14:12:20
User entered 'No (N)'	System	06 Mar 2021 14:12:20

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2021-03-06T09:12:15-05:00', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '8377730b-9163-4234-90ae-5461d792fa11'	System	06 Mar 2021 14:12:20
User entered '06 Mar 2021 09:12:15'	System	06 Mar 2021 14:12:20

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[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 (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2021-03-27T00:14:10-04:00', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'f704c8cf-4554-453f-bcdb-971489238911'	System	27 Mar 2021 04:18:14
User entered 'No (N)'	System	27 Mar 2021 04:18:14

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Have you been exposed to someone with 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 (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2021-03-27T00:14:14-04:00', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'f704c8cf-4554-453f-bcdb-971489238911'	System	27 Mar 2021 04:18:14
User entered 'No (N)'	System	27 Mar 2021 04:18:14

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2021-03-27T00:14:19-04:00', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'f704c8cf-4554-453f-bcdb-971489238911' User entered '27 Mar 2021 00:14:19'	System	27 Mar 2021 04:18:14
	System	27 Mar 2021 04:18:14

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[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 (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2021-04-07T14:00:43-04:00', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '3402a37e-cafc-4a55-9074-ad624b548beb' User entered 'No (N)'	System	10 Apr 2021 12:49:29
	System	10 Apr 2021 12:49:29

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

Have you been exposed to someone with 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 (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2021-04-07T14:00:47-04:00', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '3402a37e-cafc-4a55-9074-ad624b548beb' User entered 'No (N)'	System	10 Apr 2021 12:49:29
	System	10 Apr 2021 12:49:29

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2021-04-07T14:00:50-04:00', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '3402a37e-cafc-4a55-9074-ad624b548beb' User entered '07 Apr 2021 14:00:50'	System	10 Apr 2021 12:49:29
	System	10 Apr 2021 12:49:29

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[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 (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2021-04-10T08:49:32-04:00', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'bcbefd56-3427-40da-8450-b8bf92344bc6'	System	10 Apr 2021 12:49:50
User entered 'No (N)'	System	10 Apr 2021 12:49:50

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

Have you been exposed to someone with 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 (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2021-04-10T08:49:35-04:00', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'bcbefd56-3427-40da-8450-b8bf92344bc6'	System	10 Apr 2021 12:49:50
User entered 'No (N)'	System	10 Apr 2021 12:49:50

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2021-04-10T08:49:46-04:00', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: 'bcbefd56-3427-40da-8450-b8bf92344bc6' User entered '10 Apr 2021 08:49:46'	System	10 Apr 2021 12:49:50
	System	10 Apr 2021 12:49:50

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[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 (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2021-04-19T12:34:34-04:00', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '9e19db81-a776-44e7-bd1c-9962a2aec8ef'	System	19 Apr 2021 16:34:44
User entered 'No (N)'	System	19 Apr 2021 16:34:44

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

Have you been exposed to someone with 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 (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2021-04-19T12:34:38-04:00', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '9e19db81-a776-44e7-bd1c-9962a2aec8ef' User entered 'No (N)'	System	19 Apr 2021 16:34:44
	System	19 Apr 2021 16:34:44

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2021-04-19T12:34:41-04:00', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '9e19db81-a776-44e7-bd1c-9962a2aec8ef' User entered '19 Apr 2021 12:34:41'	System	19 Apr 2021 16:34:44
	System	19 Apr 2021 16:34:44

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[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 (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2021-04-27T13:34:49-04:00', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '71b8bc59-254a-4ef6-9b45-43799b3672d4' User entered 'No (N)'	System	27 Apr 2021 17:37:16
	System	27 Apr 2021 17:37:16

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

Have you been exposed to someone with 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 (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2021-04-27T13:34:50-04:00', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '71b8bc59-254a-4ef6-9b45-43799b3672d4' User entered 'No (N)'	System	27 Apr 2021 17:37:16

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2021-04-27T13:34:53-04:00', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '71b8bc59-254a-4ef6-9b45-43799b3672d4'	System	27 Apr 2021 17:37:16
User entered '27 Apr 2021 13:34:53'	System	27 Apr 2021 17:37:16

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[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 (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2021-05-03T12:58:40-04:00', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '72d287da-2514-41f3-8fee-11a858c1db88'	System	03 May 2021 16:58:51
User entered 'No (N)'	System	03 May 2021 16:58:51

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

Have you been exposed to someone with 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 (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2021-05-03T12:58:42-04:00', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '72d287da-2514-41f3-8fee-11a858c1db88'	System	03 May 2021 16:58:51
User entered 'No (N)'	System	03 May 2021 16:58:51

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2021-05-03T12:58:46-04:00', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '72d287da-2514-41f3-8fee-11a858c1db88'	System	03 May 2021 16:58:51
User entered '03 May 2021 12:58:46'	System	03 May 2021 16:58:51

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 14:41:46

US3352033

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:09:28

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:41:46
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 14:41:46

US3352033

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:09:28

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 08:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2021-03-01T12:08:19-05:00', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '9afed7fe-dba2-44b1-b51a-715256266495'	System	01 Mar 2021 17:20:53
User entered 'No (N)'	System	01 Mar 2021 17:20:53

US3352033

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:09:28

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:07:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1BD6D303-3BCF-4222-978D-441CBBFD3583)', Time: '2021-03-01T12:08:23-05:00', User OID: 'PatientReportedOutcome (US3352033)', ODM File OID: '9afed7fe-dba2-44b1-b51a-715256266495' User entered '01 Mar 2021 12:08:23'	System	01 Mar 2021 17:20:53
	System	01 Mar 2021 17:20:53

US3352033

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:21:08
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 18:26:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Nov 2020 17:48:01

US3352033

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:21:08
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 18:26:48
User entered '6 Nov 2020'	(b) (4), (b) (6)	06 Nov 2020 17:48:01

US3352033

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:21:08
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 18:26:48
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	06 Nov 2020 17:48:01

US3352033

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:21:08
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 18:26:48
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 17:48:01

US3352033

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:21:08
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 18:26:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Nov 2020 17:48:04

US3352033

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:21:08
User entered 'I'	System	06 Nov 2020 17:48:04

US3352033

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:24:12
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:57:08
User entered 'Yes (Y)'	Sara Gomez (b) (4)	02 Dec 2020 19:33:25
	(b) (4)	

US3352033

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:28

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:24:12
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:57:08
User entered '02 Dec 2020'	Sara Gomez (b) (4)	02 Dec 2020 19:33:25
	(b) (4)	

US3352033

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:24:12
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:57:08
User entered 'Contact Made (CONTACT MADE)'	Sara Gomez (b) (4) (b) (4)	02 Dec 2020 19:33:25

US3352033

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:24:12
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:57:08
User entered empty.	Sara Gomez (b) (4) (b) (4)	02 Dec 2020 19:33:25

US3352033

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:24:12
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:57:41
User entered 'Yes (Y)'	Sara Gomez (b) (4)	02 Dec 2020 19:33:30
	(b) (4)	

US3352033

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:24:12
User entered 'I'	System	02 Dec 2020 19:33:30

US3352033

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:24:12
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:57:48
User closed query 'Data is required. Please complete.' (Site from System).	System	08 Jan 2021 13:30:00
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Jan 2021 13:30:00
User entered 'Yes (Y)' reason for change: Data Entry Error	Yulexis Amestoy (b) (4)	08 Jan 2021 13:30:00
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Dec 2020 19:19:50
User entered empty; reason for change Data Entry Error	Yulexis Amestoy (b) (4)	28 Dec 2020 19:19:50
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4)	28 Dec 2020 19:18:12

US3352033

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:28

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:24:12
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:57:48
User entered '8 Jan 2021' reason for change: Data Entry Error	Yulexis Amestoy (b) (4)	08 Jan 2021 13:30:00
User closed query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	28 Dec 2020 19:19:50
Query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered by data change (Site from System).	System	28 Dec 2020 19:19:50
User entered empty; reason for change Data Entry Error	Yulexis Amestoy (b) (4)	28 Dec 2020 19:19:50
User opened query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	28 Dec 2020 19:18:12
User entered '28 Dec 2020'	Yulexis Amestoy (b) (4)	28 Dec 2020 19:18:12

US3352033

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:24:12
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:57:48
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error	Yulexis Amestoy (b) (4)	08 Jan 2021 13:30:00
User entered empty; reason for change Data Entry Error	Yulexis Amestoy (b) (4)	28 Dec 2020 19:19:50
User entered 'Contact Made (CONTACT MADE)'	Yulexis Amestoy (b) (4)	28 Dec 2020 19:18:12

US3352033

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:24:12
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:57:48
User entered empty.	Yulexis Amestoy (b) (4)	28 Dec 2020 19:18:12

US3352033

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:24:12
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:57:51
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4)	08 Jan 2021 13:30:06
	(b) (4)	

US3352033

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:24:12
User entered 'I'	System	08 Jan 2021 13:30:06

US3352033

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:24:12
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:00:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Feb 2021 14:16:05

US3352033

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:28

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:24:12
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:00:04
User entered '6 Feb 2021'	(b) (4), (b) (6)	06 Feb 2021 14:16:05

US3352033

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:24:12
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:00:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	06 Feb 2021 14:16:05

US3352033

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:24:12
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:00:04
User entered empty.	(b) (4), (b) (6)	06 Feb 2021 14:16:05

US3352033

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:24:12
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:00:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Feb 2021 14:15:42

US3352033

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:24:12
User entered 'I'	System	06 Feb 2021 14:15:42

US3352033

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:09:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:16:57
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:09:42
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4)	05 Mar 2021 19:29:15

US3352033

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:16:57
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:09:42
User entered '3 Mar 2021'	Yulexis Amestoy (b) (4)	05 Mar 2021 19:29:15

US3352033

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:09:28

[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 06:16:57
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:09:42
User entered 'Clinic (Clinic)'	Yulexis Amestoy (b) (4)	05 Mar 2021 19:29:15

US3352033

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:09:28

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:16:57
User entered 'VISIT4'	System	05 Mar 2021 19:29:15

US3352033

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:16:57
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:10:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Mar 2021 20:35:15

US3352033

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:16:57
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:10:04
User entered '3 Mar 2021'	(b) (4), (b) (6)	30 Mar 2021 20:35:15

US3352033

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:16:57
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:10:04
User entered '12:39'	(b) (4), (b) (6)	30 Mar 2021 20:35:15

US3352033

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:16:57
User entered '3 Mar 2021 12:39'	System	30 Mar 2021 20:35:15

US3352033

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:16:57
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:10:04
User entered '36.6' C	(b) (4), (b) (6)	30 Mar 2021 20:35:15

US3352033

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:16:57
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:10:04
User entered 'Oral (Oral)'	(b) (4), (b) (6)	30 Mar 2021 20:35:15

US3352033

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:16:57
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:10:04
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 20:35:15

US3352033

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:16:57
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:10:04
User entered '66'	(b) (4), (b) (6)	30 Mar 2021 20:35:15

US3352033

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:16:57
User entered 'bpm'	System	30 Mar 2021 20:35:15

US3352033

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:16:57
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:10:04
User entered '15'	(b) (4), (b) (6)	30 Mar 2021 20:35:15

US3352033

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:16:57
User entered 'breaths/min'	System	30 Mar 2021 20:35:15

US3352033

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:16:57
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:10:04
User entered '145'	(b) (4), (b) (6)	30 Mar 2021 20:35:15

US3352033

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:16:57
User entered 'mmHg'	System	30 Mar 2021 20:35:15

US3352033

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:16:57
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:10:04
User entered '90'	(b) (4), (b) (6)	30 Mar 2021 20:35:15

US3352033

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:16:57
User entered 'mmHg'	System	30 Mar 2021 20:35:15

US3352033

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:28

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:16:57

US3352033

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:28

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:16:57

US3352033

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:09:28

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:16:57
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:10:10
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Mar 2021 14:56:53
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4)	22 Mar 2021 15:03:48
	(b) (4)	

US3352033

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:09:28

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:16:57
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:10:10
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	26 Mar 2021 14:56:53
User entered '3 Mar 2021'	Yulexis Amestoy (b) (4)	22 Mar 2021 15:03:48
	(b) (4)	

US3352033

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:16:57
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:10:15
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4)	22 Mar 2021 15:04:13

US3352033

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:28

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:16:57
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:10:15
User entered '3 Mar 2021'	Yulexis Amestoy (b) (4)	22 Mar 2021 15:04:13

US3352033

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:28

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:16:57
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:10:15
User entered '12:59'	Yulexis Amestoy (b) (4)	22 Mar 2021 15:04:13

US3352033

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:28

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:16:57
User entered '3 Mar 2021 12:59'	System	22 Mar 2021 15:04:13

US3352033

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:16:57
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:10:19
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4)	05 Mar 2021 19:29:20

US3352033

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:16:57
User entered 'I'	System	05 Mar 2021 19:29:20

US3352033

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:01:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Apr 2021 13:57:29

US3352033

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:01:02
User entered '9 Apr 2021'	(b) (4), (b) (6)	09 Apr 2021 13:57:29

US3352033

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:01:02
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	09 Apr 2021 13:57:29

US3352033

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:01:02
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 13:57:29

US3352033

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:01:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Apr 2021 13:57:23

US3352033

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:28

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Apr 2021 13:57:23

US3352033

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

Form: Visit Date

Generated On: 09 Jun 2021 17:09:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:26:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Jan 2021 21:22:33

US3352033

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

Form: Visit Date

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:26:11
User entered '06 Jan 2021'	(b) (4), (b) (6)	06 Jan 2021 21:22:33

US3352033

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

Form: Visit Date

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:26:11
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	06 Jan 2021 21:22:33

US3352033

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

Form: Visit Date

Generated On: 09 Jun 2021 17:09:28

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User entered 'UNBLND_DECIDE'	System	06 Jan 2021 21:22:33

US3352033

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

Form: Unblinding

Generated On: 09 Jun 2021 17:09:28

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:26:51
User entered '06 Jan 2021'	(b) (4), (b) (6)	06 Jan 2021 21:22:50

US3352033

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

Form: Unblinding

Generated On: 09 Jun 2021 17:09:28

[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 15:31:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:04:16
User entered '0'	Rosaidaliz Carreira (b) (4)	08 Apr 2021 15:41:20
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 16:21:43

US3352033

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

Form: Unblinding

Generated On: 09 Jun 2021 17:09:28

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:26:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Jan 2021 21:22:50

US3352033

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

Form: Unblinding

Generated On: 09 Jun 2021 17:09:28

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:04:16
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 10:29:19
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 'Data updated.' (Site from DM).	Rosaidaliz Carreira (b) (4)	08 Apr 2021 15:41:28
User entered 'Amendment 6 or later (Amendment 6 or later)'	Rosaidaliz Carreira (b) (4)	08 Apr 2021 15:41:20
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 13:22:14
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:21:43

US3352033

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

Form: Unblinding

Generated On: 09 Jun 2021 17:09:28

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:26:51
User entered '06 Jan 2021'	(b) (4), (b) (6)	06 Jan 2021 21:22:50

US3352033

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

Form: Unblinding

Generated On: 09 Jun 2021 17:09:28

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:26:51
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	06 Jan 2021 21:22:50

US3352033

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

Form: Unblinding

Generated On: 09 Jun 2021 17:09:28

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:26:51
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 11:24:34
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	06 Jan 2021 21:22:50

US3352033

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

Form: Unblinding

Generated On: 09 Jun 2021 17:09:28

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:26:51
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 11:24:34
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	06 Jan 2021 21:22:50

US3352033

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

Form: Unblinding

Generated On: 09 Jun 2021 17:09:28

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:26:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Jan 2021 21:22:50

US3352033

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

Form: Unblinding

Generated On: 09 Jun 2021 17:09:28

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User entered '1'	System	06 Jan 2021 21:22:50

US3352033

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

Form: Unblinding

Generated On: 09 Jun 2021 17:09:28

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User entered 'I'	System	06 Jan 2021 21:22:50

US3352033

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:09:28

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:31:57
User entered '181' cm	(b) (4), (b) (6)	06 Jan 2021 21:32:59

US3352033

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:09:28

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:31:57
User entered '104.0' kg	(b) (4), (b) (6)	06 Jan 2021 21:32:59

US3352033

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:09:28

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User entered '31.74506'	System	06 Jan 2021 21:32:59
DataPoint set to visible.	System	06 Jan 2021 21:22:50

US3352033

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:09:28

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:31:57
User entered '181' cm	(b) (4), (b) (6)	06 Jan 2021 21:32:59

US3352033

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:09:28

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:31:57
User entered '104.0' kg	(b) (4), (b) (6)	06 Jan 2021 21:32:59

US3352033

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:09:28

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User entered '31.74506'	System	06 Jan 2021 21:32:59
DataPoint set to visible.	System	06 Jan 2021 21:22:50

US3352033

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:28

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	06 Jan 2021 21:32:59

US3352033

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:31:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Jan 2021 21:32:59

US3352033

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:31:57
User entered '06 Jan 2021'	(b) (4), (b) (6)	06 Jan 2021 21:32:59

US3352033

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:31:57
User entered '13:10'	(b) (4), (b) (6)	06 Jan 2021 21:32:59

US3352033

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User entered '06 Jan 2021 13:10'	System	06 Jan 2021 21:32:59

US3352033

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:31:57
User entered '37.0' C	(b) (4), (b) (6)	06 Jan 2021 21:32:59

US3352033

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:31:57
User entered 'Oral (Oral)'	(b) (4), (b) (6)	06 Jan 2021 21:32:59

US3352033

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:31:57
User entered empty.	(b) (4), (b) (6)	06 Jan 2021 21:32:59

US3352033

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:31:57
User entered '71'	(b) (4), (b) (6)	06 Jan 2021 21:32:59

US3352033

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User entered 'bpm'	System	06 Jan 2021 21:32:59

US3352033

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 13:28:28
User closed query 'Please clarify per source this is 15.' (Site from CRA).		18 Mar 2021 13:27:27
Query 'Please clarify per source this is 15.' answered with 'Updated' (Site from CRA).		02 Mar 2021 18:39:54
DataPoint Un-verified.		02 Mar 2021 18:39:49
User entered '15' reason for change: Data Entry Error		02 Mar 2021 18:39:49
DataPoint Verified.		24 Feb 2021 17:31:57
User opened query 'Please clarify per source this is 15.' (Site from CRA).		24 Feb 2021 17:28:42
User entered '16'		06 Jan 2021 21:32:59

US3352033

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User entered 'breaths/min'	System	06 Jan 2021 21:32:59

US3352033

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 13:28:28
User closed query 'Please clarify per source this is 134. ' (Site from CRA).		18 Mar 2021 13:27:31
Query 'Please clarify per source this is 134. ' answered with 'Updated' (Site from CRA).		02 Mar 2021 18:40:13
DataPoint Un-verified.		02 Mar 2021 18:40:08
User entered '134' reason for change: Per Query Resolution		02 Mar 2021 18:40:08
DataPoint Verified.		24 Feb 2021 17:31:57
User opened query 'Please clarify per source this is 134. ' (Site from CRA).		24 Feb 2021 17:28:14
User entered '138'		06 Jan 2021 21:32:59

US3352033

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User entered 'mmHg'	System	06 Jan 2021 21:32:59

US3352033

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 13:28:28
User closed query 'Please clarify per source this is 86.' (Site from CRA).		18 Mar 2021 13:27:35
Query 'Please clarify per source this is 86.' answered with 'Updated' (Site from CRA).		02 Mar 2021 18:40:30
DataPoint Un-verified.		02 Mar 2021 18:40:25
User entered '86' reason for change: Per Query Resolution		02 Mar 2021 18:40:25
DataPoint Verified.		24 Feb 2021 17:31:57
User opened query 'Please clarify per source this is 86.' (Site from CRA).		24 Feb 2021 17:28:28
User entered '82'		06 Jan 2021 21:32:59

US3352033

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User entered 'mmHg'	System	06 Jan 2021 21:32:59

US3352033

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:09:28

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:31:57
User entered '181' cm	(b) (4), (b) (6)	06 Jan 2021 21:32:59

US3352033

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:09:28

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:31:57
User entered '104.0' kg	(b) (4), (b) (6)	06 Jan 2021 21:32:59

US3352033

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:09:28

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User entered '31.74506'	System	06 Jan 2021 21:32:59
DataPoint set to visible.	System	06 Jan 2021 21:22:50

US3352033

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:28

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	06 Jan 2021 21:32:59

US3352033

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:31:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Jan 2021 21:32:59

US3352033

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:31:57
User entered '06 Jan 2021'	(b) (4), (b) (6)	06 Jan 2021 21:32:59

US3352033

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:31:57
User entered '14:26'	(b) (4), (b) (6)	06 Jan 2021 21:32:59

US3352033

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User entered '06 Jan 2021 14:26'	System	06 Jan 2021 21:32:59

US3352033

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:31:57
User entered '37.3' C	(b) (4), (b) (6)	06 Jan 2021 21:32:59

US3352033

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:31:57
User entered 'Oral (Oral)'	(b) (4), (b) (6)	06 Jan 2021 21:32:59

US3352033

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:31:57
User entered empty.	(b) (4), (b) (6)	06 Jan 2021 21:32:59

US3352033

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 13:28:28
User closed query 'Please clarify per source this is 71.' (Site from CRA).		18 Mar 2021 13:27:45
Query 'Please clarify per source this is 71.' answered with 'Updated' (Site from CRA).		02 Mar 2021 18:36:55
DataPoint Un-verified.		02 Mar 2021 18:36:48
User entered '71' reason for change: Data Entry Error		02 Mar 2021 18:36:48
DataPoint Verified.		24 Feb 2021 17:31:57
User opened query 'Please clarify per source this is 71.' (Site from CRA).		24 Feb 2021 17:30:44
User entered '79'		06 Jan 2021 21:32:59

US3352033

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User entered 'bpm'	System	06 Jan 2021 21:32:59

US3352033

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
User closed query 'Please clarify per source this is 15.' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 14:06:52
Query 'Please clarify per source this is 15.' answered with 'As per source Respiratory Rate is 16, information verified.' (Site from CRA).		19 Mar 2021 15:40:07
DataPoint Verified.		18 Mar 2021 13:28:28
User opened query 'Please clarify per source this is 15.' (Site from CRA).		18 Mar 2021 13:28:11
User closed query 'Please clarify per source this is 15.' (Site from CRA).		18 Mar 2021 13:28:11
Query 'Please clarify per source this is 15.' answered with 'Updated' (Site from CRA).		02 Mar 2021 18:38:17
DataPoint Un-verified.		02 Mar 2021 18:38:06
User entered '16' reason for change: Data Entry Error		02 Mar 2021 18:38:06
DataPoint Verified.		24 Feb 2021 17:31:57
User opened query 'Please clarify per source this is 15.' (Site from CRA).		24 Feb 2021 17:31:03
User entered '15'		06 Jan 2021 21:32:59

US3352033

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User entered 'breaths/min'	System	06 Jan 2021 21:32:59

US3352033

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 13:28:28
User closed query 'Please clarify per source this is 138.' (Site from CRA).	(b) (4), (b) (6)	18 Mar 2021 13:28:20
Query 'Please clarify per source this is 138.' answered with 'Updated' (Site from CRA).		02 Mar 2021 18:38:42
DataPoint Un-verified.		02 Mar 2021 18:38:37
User entered '138' reason for change: Per Query Resolution		02 Mar 2021 18:38:37
DataPoint Verified.		24 Feb 2021 17:31:57
User opened query 'Please clarify per source this is 138.' (Site from CRA).	(b) (4), (b) (6)	24 Feb 2021 17:31:30
User entered '134'		06 Jan 2021 21:32:59

US3352033

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User entered 'mmHg'	System	06 Jan 2021 21:32:59

US3352033

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 13:28:28
User closed query 'Please clarify per source this is 82.' (Site from CRA).		18 Mar 2021 13:28:23
Query 'Please clarify per source this is 82.' answered with 'Updated' (Site from CRA).		02 Mar 2021 18:38:59
DataPoint Un-verified.		02 Mar 2021 18:38:54
User entered '82' reason for change: Per Query Resolution		02 Mar 2021 18:38:54
DataPoint Verified.		24 Feb 2021 17:31:57
User opened query 'Please clarify per source this is 82.' (Site from CRA).		24 Feb 2021 17:31:44
User entered '86'		06 Jan 2021 21:32:59

US3352033

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User entered 'mmHg'	System	06 Jan 2021 21:32:59

US3352033

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:09:28

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:32:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Jan 2021 21:29:39

US3352033

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:09:28

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:32:11
User entered '06 Jan 2021'	(b) (4), (b) (6)	06 Jan 2021 21:29:39

US3352033

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

Form: Exposure

Generated On: 09 Jun 2021 17:09:28

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:32:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Jan 2021 21:29:54

US3352033

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

Form: Exposure

Generated On: 09 Jun 2021 17:09:28

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:32:27
User entered empty.	(b) (4), (b) (6)	06 Jan 2021 21:29:54

US3352033

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

Form: Exposure

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:32:27
User entered empty.	(b) (4), (b) (6)	06 Jan 2021 21:29:54

US3352033

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

Form: Exposure

Generated On: 09 Jun 2021 17:09:28

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User entered 'mRNA-1273'	System	06 Jan 2021 21:29:54
DataPoint set to visible.	System	06 Jan 2021 21:22:50

US3352033

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

Form: Exposure

Generated On: 09 Jun 2021 17:09:28

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:32:27
User entered '06 Jan 2021'	(b) (4), (b) (6)	06 Jan 2021 21:29:54

US3352033

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

Form: Exposure

Generated On: 09 Jun 2021 17:09:28

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:32:27
User entered '13:56'	(b) (4), (b) (6)	06 Jan 2021 21:29:54

US3352033

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

Form: Exposure

Generated On: 09 Jun 2021 17:09:28

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User entered '06 Jan 2021 13:56'	System	06 Jan 2021 21:29:54

US3352033

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

Form: Exposure

Generated On: 09 Jun 2021 17:09:28

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:32:27
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	06 Jan 2021 21:29:54

US3352033

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

Form: Exposure

Generated On: 09 Jun 2021 17:09:28

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:32:27
User entered 'ONCE'	System	06 Jan 2021 21:29:54

US3352033

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

Form: Exposure

Generated On: 09 Jun 2021 17:09:28

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User entered 'INTRAMUSCULAR'	System	06 Jan 2021 21:29:54

US3352033

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:33:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Jan 2021 21:29:28

US3352033

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:28

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:33:10
User entered '06 Jan 2021'	(b) (4), (b) (6)	06 Jan 2021 21:29:28

US3352033

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:28

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:33:10
User entered '13:42'	(b) (4), (b) (6)	06 Jan 2021 21:29:28

US3352033

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:28

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User entered '06 Jan 2021 13:42'	System	06 Jan 2021 21:29:28

US3352033

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:09:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:33:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Jan 2021 21:22:24

US3352033

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:09:28

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:33:36
User entered '06 Jan 2021'	(b) (4), (b) (6)	06 Jan 2021 21:22:24

US3352033

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:09:28

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:33:36
User entered '13:38'	(b) (4), (b) (6)	06 Jan 2021 21:22:24

US3352033

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:09:28

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User entered '06 Jan 2021 13:38'	System	06 Jan 2021 21:22:24

US3352033

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

Form: Continuing

Generated On: 09 Jun 2021 17:09:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:33:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Jan 2021 21:29:32

US3352033

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

Form: Continuing

Generated On: 09 Jun 2021 17:09:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User entered 'I'	System	06 Jan 2021 21:29:32

US3352033

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 17:10:50
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4)	13 Jan 2021 16:20:53

US3352033

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:28

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 17:10:50
User entered '13 Jan 2021'	Yulexis Amestoy (b) (4)	13 Jan 2021 16:20:53

US3352033

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 17:10:50
User entered 'Contact Made (CONTACT MADE)'	Yulexis Amestoy (b) (4)	13 Jan 2021 16:20:53

US3352033

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 17:10:50
User entered empty.	Yulexis Amestoy (b) (4)	13 Jan 2021 16:20:53

US3352033

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 17:10:56
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4)	13 Jan 2021 16:20:58

US3352033

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User entered 'I'	System	13 Jan 2021 16:20:58

US3352033

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:28

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User entered '1'	System	13 Jan 2021 16:20:58
DataPoint set to visible.	System	13 Jan 2021 16:20:58

US3352033

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:09:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:17
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:38:13
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	03 Feb 2021 20:57:09

US3352033

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:17
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:38:13
User entered '03 Feb 2021'	Matthew Muniz (b) (4)	03 Feb 2021 20:57:09

US3352033

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:17
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:38:13
User entered 'Clinic (Clinic)'	Matthew Muniz (b) (4)	03 Feb 2021 20:57:09

US3352033

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:09:28

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:17
User entered 'OLD29'	System	03 Feb 2021 20:57:09

US3352033

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:28

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:17
User accepted default value 'Pre-Dose (PREDOSE)'	Matthew Muniz (b) (4)	03 Feb 2021 20:58:04

US3352033

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:17
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:39:20
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	03 Feb 2021 20:58:04

US3352033

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:17
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:39:20
User entered '03 Feb 2021'	Matthew Muniz (b) (4)	03 Feb 2021 20:58:04

US3352033

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:17
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:39:20
User entered '13:25'	Matthew Muniz (b) (4)	03 Feb 2021 20:58:04

US3352033

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:17
User entered '03 Feb 2021 13:25'	System	03 Feb 2021 20:58:04

US3352033

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:17
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:39:20
User entered '37.0' C	Matthew Muniz (b) (4)	03 Feb 2021 20:58:04

US3352033

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:17
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:39:20
User entered 'Oral (Oral)'	Matthew Muniz (b) (4)	03 Feb 2021 20:58:04

US3352033

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:17
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:39:20
User entered empty.	Matthew Muniz (b) (4)	03 Feb 2021 20:58:04

US3352033

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:17
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:39:20
User entered '72'	Matthew Muniz (b) (4)	03 Feb 2021 20:58:04

US3352033

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:17
User entered 'bpm'	System	03 Feb 2021 20:58:04

US3352033

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:17
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:39:20
User entered '14'	Matthew Muniz (b) (4)	03 Feb 2021 20:58:04

US3352033

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:17
User entered 'breaths/min'	System	03 Feb 2021 20:58:04

US3352033

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:17
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:39:20
User entered '117'	Matthew Muniz (b) (4)	03 Feb 2021 20:58:04

US3352033

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:17
User entered 'mmHg'	System	03 Feb 2021 20:58:04

US3352033

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:17
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:39:20
User entered '76'	Matthew Muniz (b) (4)	03 Feb 2021 20:58:04

US3352033

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:09:28

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:17
User entered 'mmHg'	System	03 Feb 2021 20:58:04

US3352033

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:28

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:17
User accepted default value 'Post-Dose (POSTDOSE)'	Matthew Muniz (b) (4)	03 Feb 2021 20:58:04

US3352033

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:17
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:39:20
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	03 Feb 2021 20:58:04

US3352033

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:17
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:39:20
User entered '03 Feb 2021'	Matthew Muniz (b) (4)	03 Feb 2021 20:58:04

US3352033

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:17
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:39:20
User entered '14:25'	Matthew Muniz (b) (4)	03 Feb 2021 20:58:04

US3352033

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:17
User entered '03 Feb 2021 14:25'	System	03 Feb 2021 20:58:04

US3352033

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:17
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:39:20
User entered '36.8' C	Matthew Muniz (b) (4)	03 Feb 2021 20:58:04

US3352033

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:17
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:39:20
User entered 'Oral (Oral)'	Matthew Muniz (b) (4)	03 Feb 2021 20:58:04

US3352033

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:17
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:39:20
User entered empty.	Matthew Muniz (b) (4)	03 Feb 2021 20:58:04

US3352033

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:17
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:39:20
User entered '66'	Matthew Muniz (b) (4)	03 Feb 2021 20:58:04

US3352033

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:17
User entered 'bpm'	System	03 Feb 2021 20:58:04

US3352033

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:17
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:39:20
User entered '16'	Matthew Muniz (b) (4)	03 Feb 2021 20:58:04

US3352033

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:17
User entered 'breaths/min'	System	03 Feb 2021 20:58:04

US3352033

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:28

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:17
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:39:20
User entered '123'	Matthew Muniz (b) (4)	03 Feb 2021 20:58:04

US3352033

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:17
User entered 'mmHg'	System	03 Feb 2021 20:58:04

US3352033

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:28

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:17
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:39:20
User entered '77'	Matthew Muniz (b) (4)	03 Feb 2021 20:58:04

US3352033

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:09:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:17
User entered 'mmHg'	System	03 Feb 2021 20:58:04

US3352033

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:09:28

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:17
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:39:32
User entered 'No (N)'	Matthew Muniz (b) (4)	03 Feb 2021 20:58:07

US3352033

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:09:28

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:17
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:39:32
User entered empty.	Matthew Muniz (b) (4)	03 Feb 2021 20:58:07

US3352033

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:28

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:17
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:39:45
User closed query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	03 Feb 2021 20:58:34
Query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' answered by data change (Site from System).	System	03 Feb 2021 20:58:34
User opened query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	03 Feb 2021 20:58:09
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	03 Feb 2021 20:58:09

US3352033

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:28

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:17
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:39:45
User entered empty.	Matthew Muniz (b) (4)	03 Feb 2021 20:58:09

US3352033

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:17
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:39:45
User entered empty.	Matthew Muniz (b) (4)	03 Feb 2021 20:58:09

US3352033

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:28

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:17
User entered 'mRNA-1273'	System	03 Feb 2021 20:58:09
DataPoint set to visible.	System	13 Jan 2021 16:20:58

US3352033

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:28

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:17
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:39:45
User entered '03 Feb 2021' reason for change: Data Entry Error	Matthew Muniz (b) (4)	03 Feb 2021 20:58:34
User entered empty.	Matthew Muniz (b) (4)	03 Feb 2021 20:58:09

US3352033

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:28

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:17
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:39:45
User entered '13:55' reason for change: Data Entry Error	Matthew Muniz (b) (4)	03 Feb 2021 20:58:34
User entered empty.	Matthew Muniz (b) (4)	03 Feb 2021 20:58:09

US3352033

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:28

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:17
User entered '03 Feb 2021 13:55'	System	03 Feb 2021 20:58:34
User entered empty.	System	03 Feb 2021 20:58:09

US3352033

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:28

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:17
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:39:45
User entered 'Left Arm (LEFT ARM)' reason for change: Data Entry Error	Matthew Muniz (b) (4)	03 Feb 2021 20:58:34
User entered empty.	Matthew Muniz (b) (4)	03 Feb 2021 20:58:09

US3352033

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:28

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:17
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:39:45
User entered 'ONCE'	System	03 Feb 2021 20:58:09

US3352033

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:09:28

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:17
User entered 'INTRAMUSCULAR'	System	03 Feb 2021 20:58:09

US3352033

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:17
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:41:31
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	03 Feb 2021 20:58:36

US3352033

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:17
User entered 'I'	System	03 Feb 2021 20:58:36

US3352033

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:28

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 17:11:01
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4)	10 Feb 2021 20:45:59

US3352033

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:28

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 17:11:01
User entered '10 Feb 2021'	Yulexis Amestoy (b) (4)	10 Feb 2021 20:45:59

US3352033

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:28

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 17:11:01
User entered 'Contact Made (CONTACT MADE)'	Yulexis Amestoy (b) (4)	10 Feb 2021 20:45:59

US3352033

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:09:28

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 17:11:01
User entered empty.	Yulexis Amestoy (b) (4)	10 Feb 2021 20:45:59

US3352033

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:28

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 17:11:06
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4)	10 Feb 2021 20:45:50

US3352033

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:09:28

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User entered 'I'	System	10 Feb 2021 20:45:50

US3352033

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:09:28

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:33
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	03 Mar 2021 19:02:55

US3352033

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:33
User entered '03 Mar 2021'	Matthew Muniz (b) (4)	03 Mar 2021 19:02:55

US3352033

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:33
User entered 'Clinic (Clinic)'	Matthew Muniz (b) (4)	03 Mar 2021 19:02:55

US3352033

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:09:28

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User entered 'OLD57'	System	03 Mar 2021 19:02:55

US3352033

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:28

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:51
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	03 Mar 2021 19:03:26

US3352033

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:28

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:51
User entered '03 Mar 2021'	Matthew Muniz (b) (4)	03 Mar 2021 19:03:26

US3352033

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:51
User entered '12:39'	Matthew Muniz (b) (4)	03 Mar 2021 19:03:26

US3352033

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User entered '03 Mar 2021 12:39'	System	03 Mar 2021 19:03:26

US3352033

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:28

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:51
User entered '36.6' C	Matthew Muniz (b) (4)	03 Mar 2021 19:03:26

US3352033

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:28

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:51
User entered 'Oral (Oral)'	Matthew Muniz (b) (4)	03 Mar 2021 19:03:26

US3352033

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:28

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:51
User entered empty.	Matthew Muniz (b) (4)	03 Mar 2021 19:03:26

US3352033

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:28

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:51
User entered '66'	Matthew Muniz (b) (4)	03 Mar 2021 19:03:26

US3352033

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:28

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User entered 'bpm'	System	03 Mar 2021 19:03:26

US3352033

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:51
User entered '15'	Matthew Muniz (b) (4)	03 Mar 2021 19:03:26

US3352033

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:28

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User entered 'breaths/min'	System	03 Mar 2021 19:03:26

US3352033

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:51
User entered '145'	Matthew Muniz (b) (4)	03 Mar 2021 19:03:26

US3352033

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:28

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User entered 'mmHg'	System	03 Mar 2021 19:03:26

US3352033

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:51
User entered '90'	Matthew Muniz (b) (4)	03 Mar 2021 19:03:26

US3352033

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:28

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29
User entered 'mmHg'	System	03 Mar 2021 19:03:26

US3352033

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:28

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29

US3352033

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:09:28

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:29

US3352033

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:09:28

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:17
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:57
User closed query ' Per CDM: Please be aware that Visit 4 Day 209 and OL-D57 took place exactly the same day. However, in Visit 4 Day 209 "Was the physical examination performed?" is recorded as yes with date as '03 March 2021' but in OL-D57 ' Was the physical examination performed?' is recorded as 'no' and date is also blank. Please clarify why there is a difference or update the field. Thank you! ' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 08:00:02
Query ' Per CDM: Please be aware that Visit 4 Day 209 and OL-D57 took place exactly the same day. However, in Visit 4 Day 209 "Was the physical examination performed?" is recorded as yes with date as '03 March 2021' but in OL-D57 ' Was the physical examination performed?' is recorded as 'no' and date is also blank. Please clarify why there is a difference or update the field. Thank you! ' answered with 'The field has been updated for OL-D57 Physical Examination.' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 14:57:27
User opened query ' Per CDM: Please be aware that Visit 4 Day 209 and OL-D57 took place exactly the same day. However, in Visit 4 Day 209 "Was the physical examination performed?" is recorded as yes with date as '03 March 2021' but in OL-D57 ' Was the physical examination performed?' is recorded as 'no' and date is also blank. Please clarify why there is a difference or update the field. Thank you! ' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 10:18:28
User entered 'No (N)'	Matthew Muniz (b) (4)	03 Mar 2021 19:03:31

US3352033

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:09:28

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:17
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:08:57
User entered empty.	Matthew Muniz (b) (4)	03 Mar 2021 19:03:31

US3352033

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:28

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:17
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:09:07
User entered 'Yes (Y)'	Matthew Muniz (b) (4)	03 Mar 2021 19:02:39

US3352033

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:28

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:17
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:09:07
User entered '03 Mar 2021'	Matthew Muniz (b) (4)	03 Mar 2021 19:02:39

US3352033

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:28

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:17
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:09:07
User entered '12:59'	Matthew Muniz (b) (4)	03 Mar 2021 19:02:39

US3352033

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:09:28

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:31:17
User entered '03 Mar 2021 12:59'	System	03 Mar 2021 19:02:39

US3352033

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:09:28

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:51:31
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:53:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 20:56:05

US3352033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:28

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:27:22
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:07:57
User entered 'USA-US066-2020-mRNA-1273-P301000004'	System	09 Nov 2020 18:07:52
User entered 'New'	(b) (4), (b) (6)	09 Nov 2020 18:07:52

US3352033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:28

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:29:39
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Acute myocardial infarction, LLT: Acute myocardial infarction, of other inferior wall - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 20:42:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 20:42:50
Data point term sent to Coder	System	17 Nov 2020 20:10:42
Coding entries removed.	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 20:10:13
User entered 'ACUTE INFERIOR WALL MYOCARDIAL INFARCTION' reason for change: New Information	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 20:10:13
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Myocardial infarction, LLT: Myocardial infarction - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 17:52:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 17:52:30
Data point term sent to Coder	System	06 Nov 2020 17:51:54
User entered 'MYOCARDIAL INFARCTION'	(b) (4), (b) (6) (b) (4)	06 Nov 2020 17:51:33

US3352033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:28

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:29:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Nov 2020 17:51:33

US3352033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:28

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:29:48
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 17:51:33

US3352033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:28

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:29:50
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 17:51:33

US3352033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 18:52:35
DataPoint Un-verified.	Matthew Muniz (b) (4)	07 Dec 2020 15:32:44
User entered '05 Nov 2020' reason for change: Data Entry Error	Matthew Muniz (b) (4)	07 Dec 2020 15:32:44
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:29:58
User entered '5 Nov 2020'	(b) (4), (b) (6)	06 Nov 2020 17:51:33

US3352033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:28

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:30:01
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 17:51:33

US3352033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:28

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 17:51:33

US3352033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:28

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:30:04
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 17:51:33

US3352033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:28

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:30:07
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	06 Nov 2020 17:52:47
User entered '05 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 17:52:47
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	06 Nov 2020 17:52:06
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	06 Nov 2020 17:52:06
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	06 Nov 2020 17:52:06
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 17:52:06
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	06 Nov 2020 17:51:33
User entered '5 Nov 2020'	(b) (4), (b) (6)	06 Nov 2020 17:51:33

US3352033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:28

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:30:10
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 17:51:33

US3352033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:28

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 17:51:33

US3352033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:28

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:30:13
User entered 'Grade 4 (Grade 4)' reason for change:	Rosaidaliz Carreira (b) (4)	12 Nov 2020 15:56:31
New Information	(b) (4)	
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	06 Nov 2020 17:51:33

US3352033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:28

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:30:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Nov 2020 17:51:33

US3352033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:28

Death

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:30:19
User entered '0'	(b) (4), (b) (6)	06 Nov 2020 17:51:33

US3352033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:28

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:30:21
User entered '0'	(b) (4), (b) (6)	06 Nov 2020 17:51:33

US3352033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:30:24
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	09 Nov 2020 05:54:15
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Subject still admitted in the hospital' (Site from System).	(b) (4), (b) (6)	06 Nov 2020 17:53:33
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	06 Nov 2020 17:51:33
User entered 'I'	(b) (4), (b) (6)	06 Nov 2020 17:51:33

US3352033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:28

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:30:28
User entered '5 Nov 2020'	(b) (4), (b) (6)	06 Nov 2020 17:51:33

US3352033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:28

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:30:30
User closed query 'Per CDM-Hospital discharge date is recorded as '10 NOV 2020',however Ae end date is recorded as 5 NOV 2020'.Kindly consider to verify and update data recorded else clarify.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 06:41:20
Query 'Per CDM-Hospital discharge date is recorded as '10 NOV 2020',however Ae end date is recorded as 5 NOV 2020'.Kindly consider to verify and update data recorded else clarify.' answered with 'SUBJECT WAS ADMITTED FOR FURTHER EVALUATIONS. ACUTE MI WAS 05NOV2020. ' (Site from DM).	Rosaidaliz Carreira (b) (4)	17 Nov 2020 20:05:52
User opened query 'Per CDM-Hospital discharge date is recorded as '10 NOV 2020',however Ae end date is recorded as 5 NOV 2020'.Kindly consider to verify and update data recorded else clarify.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 06:28:23
User closed query 'Per CDM-Kindly consider to update hospital discharge date when data is available.Thank you.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 06:24:11
Query 'Per CDM-Kindly consider to update hospital discharge date when data is available.Thank you.' answered with 'Data has been updated.' (Site from DM).	Rosaidaliz Carreira (b) (4)	12 Nov 2020 15:55:25
User entered '10 Nov 2020' reason for change: New Information	Rosaidaliz Carreira (b) (4)	12 Nov 2020 15:55:09
User opened query 'Per CDM-Kindly consider to update hospital discharge date when data is available.Thank you.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 14:54:05
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 17:51:33

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:28

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:30:33
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 17:51:33

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:28

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:30:35
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 17:51:33

US3352033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:30:37
User entered '0'	(b) (4), (b) (6)	06 Nov 2020 17:51:33

US3352033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:28

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:30:38
User entered '0'	(b) (4), (b) (6)	06 Nov 2020 17:51:33

US3352033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:28

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:30:47
User entered '0'	(b) (4), (b) (6)	06 Nov 2020 17:51:33

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:28

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:30:49
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	06 Nov 2020 17:51:33

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:28

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:30:51
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	06 Nov 2020 17:51:33

US3352033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:28

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:30:54
User closed query 'PV Query: As the event occurred after the second dose of the study drug, please update the action taken with {study drug} from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 21:50:58
Query 'PV Query: As the event occurred after the second dose of the study drug, please update the action taken with {study drug} from none to not applicable.' answered with 'Data updated ' (Site from Safety).	Wanda Delgado (b) (4)	20 Nov 2020 16:43:26
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Wanda Delgado (b) (4)	20 Nov 2020 16:42:51
User opened query 'PV Query: As the event occurred after the second dose of the study drug, please update the action taken with {study drug} from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 15:08:59
User entered 'None (NONE)'	(b) (4), (b) (6)	06 Nov 2020 17:51:33

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:28

None

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:30:59
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	06 Nov 2020 17:54:05
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	06 Nov 2020 17:51:33
User entered '0'	(b) (4), (b) (6)	06 Nov 2020 17:51:33

US3352033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:28

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 18:51:35
User closed query 'Per medical record subject was given lidocaine 2% topically for procedure of Angioplasty with stent on 05DEC2020, and 09DEC2020 please verify in ConMed page in source. Per Hospital record there was no medication given for SAE. This should be no, Please clarify. ' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 18:51:32
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 06:47:45
Query 'Per medical record subject was given lidocaine 2% topically for procedure of Angioplasty with stent on 05DEC2020, and 09DEC2020 please verify in ConMed page in source. Per Hospital record there was no medication given for SAE. This should be no, Please clarify. ' answered with 'Added to CC med' (Site from CRA).	Rosaidaliz Carreira (b) (4)	25 Jan 2021 21:25:42
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'Data updated' (Site from DM).	Rosaidaliz Carreira (b) (4)	25 Jan 2021 21:25:31
DataPoint Un-verified.	Rosaidaliz Carreira (b) (4)	25 Jan 2021 21:25:03
User entered '0' reason for change: Data Entry Error	Rosaidaliz Carreira (b) (4)	25 Jan 2021 21:25:03

US3352033

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:28

[Concomitant Medication](#)

Audit	User	Time (GMT)
User opened query 'Per medical record subject was given lidocaine 2% topically for procedure of Angioplasty with stent on 05DEC2020, and 09DEC2020 please verify in ConMed page in source. Per Hospital record there was no medication given for SAE. This should be no, Please clarify. ' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 21:38:59
	(b) (4), (b) (6)	03 Dec 2020 16:31:00
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 10:10:12
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 17:54:05
User entered '0'	(b) (4), (b) (6)	06 Nov 2020 17:51:33

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:28

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
User closed query 'Per DM CLR: Please review response as there is a Concomitant Procedure recorded that matches this AE during this timeframe. Please review and update this field.' (Site from DM). Query 'Per DM CLR: Please review response as there is a Concomitant Procedure recorded that matches this AE during this timeframe. Please review and update this field.' answered with 'Data correct' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 06:47:40
Query 'This should be checked. Per source in medical record subject had Chest Xray and Transthoracic Echocardiogram 05NOV2020, please add these to Concomitant Procedures page.' canceled (Site from CRA).	Rosaidaliz Carreira (b) (4) (b) (4)	25 Jan 2021 21:26:05
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 21:32:15
DataPoint Un-verified.	(b) (4), (b) (6)	11 Jan 2021 15:22:27
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Dec 2020 13:44:39
User opened query 'Per DM CLR: Please review response as there is a Concomitant Procedure recorded that matches this AE during this timeframe. Please review and update this field.' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 13:44:39
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 10:03:35
User opened query 'This should be checked. Per source in medical record subject had Chest Xray and Transthoracic Echocardiogram 05NOV2020, please add these to Concomitant Procedures page.' (Site from CRA).	(b) (4), (b) (6)	03 Dec 2020 16:33:49
User entered '0'	(b) (4), (b) (6)	03 Dec 2020 16:33:46
	(b) (4), (b) (6)	06 Nov 2020 17:51:33

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:28

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:33:51
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 17:52:47
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	06 Nov 2020 17:51:33

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:33:53
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 17:51:33

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:28

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
User closed query 'PV Query: Discharge summary was not received. Please resend a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Mar 2021 14:38:18
Query 'PV Query: Discharge summary was not received. Please resend a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'Records have been sent.' (Site from Safety).	(b) (4), (b) (6)	26 Mar 2021 14:57:53
User opened query 'PV Query: Discharge summary was not received. Please resend a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	22 Feb 2021 20:02:54
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	22 Feb 2021 16:33:13
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'all medical records and discharge were sent ' (Site from Safety).	Sara Gomez (b) (4) (b) (4)	20 Feb 2021 16:25:50

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:28

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please confirm the start date of hypertension, hyperlipidemia, and acute inferior wall myocardial infarction which are included in medical history. If medical history of acute inferior wall myocardial infarction is the same as the reported event, it should be removed from medical history. Since hypertension and hyperlipidemia were reported as underlying conditions of the event, reconsideration of start date may be required.' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 13:53:51
Query 'PV Query: Please confirm the start date of hypertension, hyperlipidemia, and acute inferior wall myocardial infarction which are included in medical history. If medical history of acute inferior wall myocardial infarction is the same as the reported event, it should be removed from medical history. Since hypertension and hyperlipidemia were reported as underlying conditions of the event, reconsideration of start date may be required.' answered with 'correct as entered' (Site from Safety).	Sara Gomez (b) (4) (b) (4)	18 Feb 2021 21:27:17
User opened query 'PV Query: Please confirm the start date of hypertension, hyperlipidemia, and acute inferior wall myocardial infarction which are included in medical history. If medical history of acute inferior wall myocardial infarction is the same as the reported event, it should be removed from medical history. Since hypertension and hyperlipidemia were reported as underlying conditions of the event, reconsideration of start date may be required.' (Site from Safety).	(b) (4), (b) (6)	28 Dec 2020 15:45:29
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:34:48
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Nov 2020 21:32:40
User closed query 'PV Query: Please provide hospital discharge summary with all patient identifiers redacted to Safety_Moderna@iqvia.com or fax to 1-866-599-1342.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 21:49:48

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide hospital discharge summary with all patient identifiers redacted to Safety_Moderna@iqvia.com or fax to 1-866-599-1342.' answered with 'Pending records, once received we'll redacted identifiers and send to Safety_Moderna@iqvia.com or fax to 1-866-599-1342.' (Site from Safety).	Wanda Delgado (b) (4)	20 Nov 2020 16:45:02
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)	18 Nov 2020 22:05:34
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	18 Nov 2020 22:05:21
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	18 Nov 2020 22:05:14
User closed query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	18 Nov 2020 22:05:06
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 'NO COVID-19 TEST DONE AS PER MEDICAL RECORDS.' (Site from Safety).	Rosaidaliz Carreira (b) (4)	17 Nov 2020 21:01:07
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'PLEASE REFER TO CON MED FORMS.' (Site from Safety).	Rosaidaliz Carreira (b) (4)	17 Nov 2020 20:11:10

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:28

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'TROPONIN I 4.110 NG/ML ALSO POC ACTIVE COAGULATION TIME 278 SECONDS.' (Site from Safety).	Rosaidaliz Carreira (b) (4)	17 Nov 2020 20:10:01
Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' answered with 'HYPERTENSION AND HYPERLIPIDEMIA WHICH WAS NOT REPORTED DURING SCREENING VISIT. MEDICAL HISTORY WILL BE UPDATED.' (Site from Safety).	Rosaidaliz Carreira (b) (4)	17 Nov 2020 20:06:41
User opened query 'PV Query: Please provide hospital discharge summary with all patient identifiers redacted to Safety_Moderna@iqvia.com or fax to 1-866-599-1342.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 13:27:07
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)	13 Nov 2020 13:26:08
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)	13 Nov 2020 13:25:57
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 13:25:50
User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 13:25:44
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	06 Nov 2020 17:58:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:28

[Narrative](#)

Audit	User	Time (GMT)
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	06 Nov 2020 17:58:04
User entered 'The subject started chest pains at 3 am on 05NOV2020. Went to the ER and was diagnosed with myocardial infarction. He remains hospitalized. The subject reported feeling better today, with no COVID-19 symptoms. Pending medical records.' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 17:58:04
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	06 Nov 2020 17:51:33
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 17:51:33

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:28

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 17:51:33

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:28

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	06 Nov 2020 17:51:33

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:09:28

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	06 Nov 2020 17:51:33

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:09:28

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:51:31
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:55:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Aug 2020 19:51:56

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:09:28

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:56:20
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Aug 2020 19:54:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Aug 2020 19:54:08
Data point term sent to Coder	System	06 Aug 2020 19:53:17
User entered 'ADVIL'	(b) (4), (b) (6)	06 Aug 2020 19:52:49

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:09:28

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:56:20
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 19:52:49

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:09:28

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:56:20
User entered 'MIGRAINES'	(b) (4), (b) (6)	06 Aug 2020 19:52:49

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:09:28

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:56:20
User entered '400'	(b) (4), (b) (6)	06 Aug 2020 19:52:49

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:09:28

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:56:20
User entered 'mg (mg)'	(b) (4), (b) (6)	06 Aug 2020 19:52:49

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:09:28

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:56:20
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 19:52:49

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:09:28

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:56:20
User entered 'as needed (PRN)'	(b) (4), (b) (6)	06 Aug 2020 19:52:49

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:09:28

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:56:20
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 19:52:49

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:09:28

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:56:20
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	06 Aug 2020 19:52:49

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:09:28

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:56:20
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 19:52:49

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:09:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:56:20
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 17:16:36
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' (Site from System).	(b) (4), (b) (6)	06 Aug 2020 19:53:17
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 19:52:49
User entered 'UN UNK 2015'	(b) (4), (b) (6)	06 Aug 2020 19:52:49

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:09:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:56:20
User entered '0'	(b) (4), (b) (6)	06 Aug 2020 19:52:49

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:09:28

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:56:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Aug 2020 19:52:49

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:09:28

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:56:20
User entered empty.	(b) (4), (b) (6)	06 Aug 2020 19:52:49

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:09:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:56:20
User entered 'No (N)'	(b) (4), (b) (6)	06 Aug 2020 19:52:49

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:09:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 19:52:49

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:09:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 19:52:49

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:09:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 19:52:49

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:09:28

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:56:20
User closed query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med name, #1 ADVIL (UN UNK 2015-ongoing). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 18:45:07
Query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med name, #1 ADVIL (UN UNK 2015-ongoing). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' answered with 'data correct as entered' (Site from DM).	Matthew Muniz (b) (4)	02 Oct 2020 14:09:26
User opened query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med name, #1 ADVIL (UN UNK 2015-ongoing). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 07:19:01
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 00:11:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 00:11:58
Data point term sent to Coder	System	14 Aug 2020 19:56:12
User entered 'ADVIL'	(b) (4), (b) (6)	14 Aug 2020 19:55:49

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:09:28

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:56:20
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 19:55:49

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:09:28

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:56:20
User entered 'NECK PAIN'	(b) (4), (b) (6)	14 Aug 2020 19:55:49

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:09:28

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:56:20
User entered '400'	(b) (4), (b) (6)	14 Aug 2020 19:55:49

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:09:28

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:56:20
User entered 'mg (mg)'	(b) (4), (b) (6)	14 Aug 2020 19:55:49

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:09:28

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:56:20
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 19:55:49

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:09:28

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:56:20
User entered 'as needed (PRN)'	(b) (4), (b) (6)	14 Aug 2020 19:55:49

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:09:28

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:56:20
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 19:55:49

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:09:28

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:56:20
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	14 Aug 2020 19:55:49

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:09:28

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:56:20
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 19:55:49

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:09:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:56:20
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)	16 Aug 2020 12:52:43
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 ' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 19:56:08
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	14 Aug 2020 19:55:49
User entered 'UN UNK 2014'	(b) (4), (b) (6)	14 Aug 2020 19:55:49

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:09:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:56:20
User entered '0'	(b) (4), (b) (6)	14 Aug 2020 19:55:49

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:09:28

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:56:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Aug 2020 19:55:49

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:56:20
User entered empty.	(b) (4), (b) (6)	14 Aug 2020 19:55:49

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:09:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	07 Oct 2020 16:56:20
User entered 'No (N)'	(b) (4), (b) (6)	14 Aug 2020 19:55:49

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:09:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 19:55:49

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:09:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 19:55:49

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:09:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Aug 2020 19:55:49

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:09:28

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: TICAGRELOR, PRODUCTSYNONYM: BRILINTA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Jan 2021 17:22:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Jan 2021 17:22:39
Data point term sent to Coder	System	11 Jan 2021 17:21:32
Coding entries removed.	Matthew Muniz (b) (4)	11 Jan 2021 17:20:43
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: TICAGRELOR, PRODUCTSYNONYM: BRILINTA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Dec 2020 15:46:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Dec 2020 15:46:22
Data point term sent to Coder	System	07 Dec 2020 15:44:33
Coding entries removed.	Matthew Muniz (b) (4)	07 Dec 2020 15:43:56
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:45:57
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: TICAGRELOR, PRODUCTSYNONYM: BRILINTA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Nov 2020 20:20:49

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:09:28

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	17 Nov 2020 20:20:49
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	17 Nov 2020 20:19:55
User entered 'BRILINTA'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 20:18:57
	(b) (4)	

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:09:28

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 21:33:04
DataPoint Un-verified.	Matthew Muniz (b) (4)	11 Jan 2021 17:20:43
User entered 'Yes (Y)' reason for change: Data Entry Error	Matthew Muniz (b) (4)	11 Jan 2021 17:20:43
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:45:58
User entered 'No (N)'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 20:18:57

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:09:28

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 21:33:04
User closed query 'Please clarify, if AE ended on 05NOV2020 then why is subject still taking this medication? This medication is usually used as a cardiovascular prophylaxis which prevents cardiovascular events like acute inferior wall myocardial infarction. Does this medication have an end date of 05NOV2020, like the AE it is indicated for or is this ongoing which would mean it has a different indication like Cardiovascular prophylaxis?' (Site from CRA).	(b) (4), (b) (6)	13 Jan 2021 21:32:58
Query 'Please clarify, if AE ended on 05NOV2020 then why is subject still taking this medication? This medication is usually used as a cardiovascular prophylaxis which prevents cardiovascular events like acute inferior wall myocardial infarction. Does this medication have an end date of 05NOV2020, like the AE it is indicated for or is this ongoing which would mean it has a different indication like Cardiovascular prophylaxis?' answered with 'updated' (Site from CRA).	Matthew Muniz (b) (4)	11 Jan 2021 17:21:03
DataPoint Un-verified.	Matthew Muniz (b) (4)	11 Jan 2021 17:20:43
User entered 'cardiovascular prophylaxis' reason for change: Data Entry Error	Matthew Muniz (b) (4)	11 Jan 2021 17:20:43
DataPoint Verified.	(b) (4), (b) (6)	11 Jan 2021 15:12:35
User opened query 'Please clarify, if AE ended on 05NOV2020 then why is subject still taking this medication? This medication is usually used as a cardiovascular prophylaxis which prevents cardiovascular events like acute inferior wall myocardial infarction. Does this medication have an end date of 05NOV2020, like the AE it is indicated for or is this ongoing which would mean it has a different indication like Cardiovascular prophylaxis?' (Site from CRA).	(b) (4), (b) (6)	11 Jan 2021 15:11:59

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:09:28

[Indication](#)

Audit	User	Time (GMT)
Query 'Please clarify, if AE ended on 05NOV2020 then why is subject still taking this medication. This medication is usually used as a cardiovascular prophylaxis which prevents cardiovascular events like acute inferior wall myocardial infarction. Does this medication have an end date of 05NOV2020, like the AE it is indicated for or is this ongoing which would mean it has a different indication like Cardiovascular prophylaxis?' canceled (Site from CRA).	(b) (4), (b) (6)	11 Jan 2021 15:11:36
User opened query 'Please clarify, if AE ended on 05NOV2020 then why is subject still taking this medication. This medication is usually used as a cardiovascular prophylaxis which prevents cardiovascular events like acute inferior wall myocardial infarction. Does this medication have an end date of 05NOV2020, like the AE it is indicated for or is this ongoing which would mean it has a different indication like Cardiovascular prophylaxis?' (Site from CRA).	(b) (4), (b) (6)	11 Jan 2021 15:11:33
Query 'Please clarify, if AE ended on 05NOV2020 then why is subject still taking this medication? This medication is usually used as a cardiovascular prophylaxis which prevents cardiovascular events like acute inferior wall myocardial infarction. Does this medication have an end date of 10NOV2020, like the AE it is indicated for or is this ongoing which would mean it has a different indication like Cardiovascular prophylaxis?' canceled (Site from CRA).	(b) (4), (b) (6)	11 Jan 2021 15:11:14
User opened query 'Please clarify, if AE ended on 05NOV2020 then why is subject still taking this medication? This medication is usually used as a cardiovascular prophylaxis which prevents cardiovascular events like acute inferior wall myocardial infarction. Does this medication have an end date of 10NOV2020, like the AE it is indicated for or is this ongoing which would mean it has a different indication like Cardiovascular prophylaxis?' (Site from CRA).	(b) (4), (b) (6)	11 Jan 2021 15:10:15

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:09:28

[Indication](#)

Audit	User	Time (GMT)
Query 'Please clarify, if AE ended on 05NOV2020 then why is subject still taking this medication. This medication is usually used as a cardiovascular prophylaxis which prevents cardiovascular events like acute inferior wall myocardial infarction. Does this medication have an end date of 10NOV2020, like the AE it is indicated for or is this ongoing which would mean it has a different indication like Cardiovascular prophylaxis?' canceled (Site from CRA).	(b) (4), (b) (6)	11 Jan 2021 15:09:58
User opened query 'Please clarify, if AE ended on 05NOV2020 then why is subject still taking this medication. This medication is usually used as a cardiovascular prophylaxis which prevents cardiovascular events like acute inferior wall myocardial infarction. Does this medication have an end date of 10NOV2020, like the AE it is indicated for or is this ongoing which would mean it has a different indication like Cardiovascular prophylaxis?' (Site from CRA).	(b) (4), (b) (6)	11 Jan 2021 15:09:48
Query 'Please clarify, if AE ended on 10NOV2020 then why is subject still taking this medication. This medication is usually used as a cardiovascular prophylaxis which prevents cardiovascular events like acute inferior wall myocardial infarction. Does this medication have an end date of 10NOV2020, like the AE it is indicated for or is this ongoing which would mean it has a different indication like Cardiovascular prophylaxis?' canceled (Site from CRA).	(b) (4), (b) (6)	11 Jan 2021 15:09:15
User opened query 'Please clarify, if AE ended on 10NOV2020 then why is subject still taking this medication. This medication is usually used as a cardiovascular prophylaxis which prevents cardiovascular events like acute inferior wall myocardial infarction. Does this medication have an end date of 10NOV2020, like the AE it is indicated for or is this ongoing which would mean it has a different indication like Cardiovascular prophylaxis?' (Site from CRA).	(b) (4), (b) (6)	11 Jan 2021 15:07:22

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:09:28

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Please clarify if this is being used for cardiovascular prophylaxis? The AE ended on 10NOV2020 and this medication is used to prevent cardiovascular events. Please update source appropriately. ' (Site from CRA).	(b) (4), (b) (6)	11 Jan 2021 15:07:22
Query 'Please clarify if this is being used for cardiovascular prophylaxis? The AE ended on 10NOV2020 and this medication is used to prevent cardiovascular events. Please update source appropriately. ' answered with 'updated' (Site from CRA).	Matthew Muniz (b) (4)	07 Dec 2020 15:44:02
DataPoint Un-verified.	Matthew Muniz (b) (4)	07 Dec 2020 15:43:56
User entered 'ACUTE INFERIOR WALL MYOCARDIAL INFARCTION' reason for change: Data Entry Error	Matthew Muniz (b) (4)	07 Dec 2020 15:43:56
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:46:01
User opened query 'Please clarify if this is being used for cardiovascular prophylaxis? The AE ended on 10NOV2020 and this medication is used to prevent cardiovascular events. Please update source appropriately. ' (Site from CRA).	(b) (4), (b) (6)	03 Dec 2020 16:42:12
User entered 'INFERIOR INFARCTION'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 20:18:57

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:09:28

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:46:03
User entered '90'	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 20:18:57

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:09:28

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:46:05
User entered 'mg (mg)'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 20:18:57
	(b) (4)	

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:09:28

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:46:07
User entered empty.	Rosaidaliz Carreira (b) (4)	17 Nov 2020 20:18:57
	(b) (4)	

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:09:28

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:46:08
User entered 'twice daily (BID)'	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 20:18:57

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:09:28

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:46:11
User entered empty.	Rosaidaliz Carreira (b) (4)	17 Nov 2020 20:18:57
	(b) (4)	

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:09:28

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:46:13
User entered 'Oral (ORAL)'	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 20:18:57

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:09:28

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:46:15
User entered empty.	Rosaidaliz Carreira (b) (4)	17 Nov 2020 20:18:57
	(b) (4)	

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:09:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	11 Jan 2021 15:12:45
User closed query 'Per DM CLR: The Con Med start date is after the resolution date of the corresponding AE ACUTE INFERIOR WALL MYOCARDIAL INFARCTION (5 NOV 2020 - 5 NOV 2020). Please determine if an additional AE should be recorded for this condition or if the current AE dates should be corrected. Please reconcile Con Med and AE eCRFs as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 06:26:06
Query 'Per DM CLR: The Con Med start date is after the resolution date of the corresponding AE ACUTE INFERIOR WALL MYOCARDIAL INFARCTION (5 NOV 2020 - 5 NOV 2020). Please determine if an additional AE should be recorded for this condition or if the current AE dates should be corrected. Please reconcile Con Med and AE eCRFs as appropriate. ' answered with 'updated' (Site from DM).	Matthew Muniz (b) (4)	07 Dec 2020 15:42:13
DataPoint Un-verified.	Matthew Muniz (b) (4)	07 Dec 2020 15:42:06
User entered '05 Nov 2020' reason for change: Data Entry Error	Matthew Muniz (b) (4)	07 Dec 2020 15:42:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:48:05
User opened query 'Per DM CLR: The Con Med start date is after the resolution date of the corresponding AE ACUTE INFERIOR WALL MYOCARDIAL INFARCTION (5 NOV 2020 - 5 NOV 2020). Please determine if an additional AE should be recorded for this condition or if the current AE dates should be corrected. Please reconcile Con Med and AE eCRFs as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 16:02:24
User entered '10 Nov 2020'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 20:18:57

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:09:28

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:48:09
User entered '0'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 20:18:57
	(b) (4)	

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:09:28

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:48:11
User entered 'Yes (Y)'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 20:18:57
	(b) (4)	

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:48:13
User entered empty.	Rosaidaliz Carreira (b) (4)	17 Nov 2020 20:18:57
	(b) (4)	

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:09:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:48:15
User entered 'No (N)'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 20:18:57
	(b) (4)	

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:09:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	17 Nov 2020 20:18:57

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:09:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Nov 2020 20:18:57

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:09:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Nov 2020 20:18:57

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:09:28

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 21:33:04
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN, PRODUCTSYNONYM: LIPITOR [ATORVASTATIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 20:21:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 20:21:50
Data point term sent to Coder User entered 'LIPITOR'	System Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 20:20:57 17 Nov 2020 20:20:26

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:09:28

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 21:33:04
User entered 'No (N)'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 20:20:26

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:09:28

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 21:33:04
User closed query ' Per DM CLR Requery-Response noted as updated,however, still there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 07:39:45
Query ' Per DM CLR Requery-Response noted as updated,however, still there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.' answered with 'medical history updated ' (Site from DM).	Matthew Muniz (b) (4)	09 Dec 2020 14:07:24
User opened query ' Per DM CLR Requery-Response noted as updated,however, still there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 06:29:55
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 06:29:55
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.' answered with 'updated' (Site from DM).	Matthew Muniz (b) (4)	07 Dec 2020 15:56:28
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 16:02:59
User entered 'HYPERLIPIDEMIA'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 20:20:26

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:09:28

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 21:33:04
User entered '40'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 20:20:26
	(b) (4)	

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:09:28

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 21:33:04
User entered 'mg (mg)'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 20:20:26
	(b) (4)	

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:09:28

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 21:33:04
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 20:20:26

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:09:28

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 21:33:04
User closed query 'Per CDM: Please consider selecting "Once daily" from the dropdown instead of selecting Other and writing "Everyday at bedtime". Thank you!' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 11:55:06
User closed query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	System	30 Nov 2020 18:28:44
Query 'Per CDM: Please consider selecting "Once daily" from the dropdown instead of selecting Other and writing "Everyday at bedtime". Thank you!' answered with 'updated' (Site from DM).	Matthew Muniz (b) (4)	30 Nov 2020 18:28:32
User opened query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	System	30 Nov 2020 18:26:57
User entered 'once daily (QD)' reason for change: Data Entry Error	Matthew Muniz (b) (4)	30 Nov 2020 18:26:57
User opened query 'Per CDM: Please consider selecting "Once daily" from the dropdown instead of selecting Other and writing "Everyday at bedtime". Thank you!' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 11:16:25
User entered 'other (OTHER)'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 20:20:26

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:09:28

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 21:33:04
User entered empty; reason for change Data Entry Error	Matthew Muniz (b) (4)	30 Nov 2020 18:28:44
User entered 'EVERYDAY AT BEDTIME'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 20:20:26

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:09:28

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 21:33:04
User entered 'Oral (ORAL)'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 20:20:26

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:09:28

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 21:33:04
User entered empty.	Rosaidaliz Carreira (b) (4)	17 Nov 2020 20:20:26
	(b) (4)	

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:09:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 21:33:04
User entered '10 Nov 2020'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 20:20:26
	(b) (4)	

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:09:28

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 21:33:04
User entered '0'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 20:20:26
	(b) (4)	

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:09:28

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 21:33:04
User entered 'Yes (Y)'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 20:20:26

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 21:33:04
User entered empty.	Rosaidaliz Carreira (b) (4)	17 Nov 2020 20:20:26
	(b) (4)	

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:09:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 21:33:04
User entered 'No (N)'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 20:20:26

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:09:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Nov 2020 18:26:57
User entered empty.	System	17 Nov 2020 20:20:26

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:09:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Nov 2020 18:26:57
User entered empty.	System	17 Nov 2020 20:20:26

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:09:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Nov 2020 18:26:57
User entered empty.	System	17 Nov 2020 20:20:26

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:09:28

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Dec 2020 16:03:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Dec 2020 16:03:45
Data point term sent to Coder Coding entries removed.	System Matthew Muniz (b) (4)	07 Dec 2020 16:02:42 07 Dec 2020 16:02:03
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:48:48
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 20:22:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 20:22:51
Data point term sent to Coder User entered 'METOPROLOL'	System Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 20:21:59 17 Nov 2020 20:21:34

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:09:28

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
Un-reviewed for Data Management.	(b) (4), (b) (6)	26 Jan 2021 10:04:08
Reviewed for Data Management.	(b) (4), (b) (6)	26 Jan 2021 10:04:04
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:48:50
User entered 'No (N)'	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 20:21:34

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:09:28

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 21:33:04
User closed query 'Per DM CLR Requery-Response noted as updated,however, still there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 07:40:13
Query 'Per DM CLR Requery-Response noted as updated,however, still there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' answered with 'medical history updated ' (Site from DM).	Matthew Muniz (b) (4)	09 Dec 2020 14:07:51
User opened query 'Per DM CLR Requery-Response noted as updated,however, still there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 06:31:20
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 06:31:20
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.' answered with 'updated' (Site from DM).	Matthew Muniz (b) (4)	07 Dec 2020 16:02:10
DataPoint Un-verified.	Matthew Muniz (b) (4)	07 Dec 2020 16:02:03
User entered 'hypertension' reason for change: Data Entry Error	Matthew Muniz (b) (4)	07 Dec 2020 16:02:03
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:48:51

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:09:28

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 16:03:36
User entered 'VENTRICULAR TACHYCARDIA'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 20:21:34

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:09:28

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:48:54
User entered '12.5'	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 20:21:34

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:09:28

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:48:58
User entered 'mg (mg)'	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 20:21:34

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:09:28

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:48:59
User entered empty.	Rosaidaliz Carreira (b) (4)	17 Nov 2020 20:21:34
	(b) (4)	

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:09:28

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:49:01
User entered 'twice daily (BID)'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 20:21:34
	(b) (4)	

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:09:28

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:49:02
User entered empty.	Rosaidaliz Carreira (b) (4)	17 Nov 2020 20:21:34
	(b) (4)	

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:09:28

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:49:06
User entered 'Oral (ORAL)'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 20:21:34
	(b) (4)	

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:09:28

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:49:08
User entered empty.	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 20:21:34

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:09:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:49:09
User entered '10 Nov 2020'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 20:21:34
	(b) (4)	

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:09:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:49:11
User entered '0'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 20:21:34
	(b) (4)	

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:09:28

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:49:13
User entered 'Yes (Y)'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 20:21:34
	(b) (4)	

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:49:15
User entered empty.	Rosaidaliz Carreira (b) (4)	17 Nov 2020 20:21:34
	(b) (4)	

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:09:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:49:16
User entered 'No (N)'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 20:21:34
	(b) (4)	

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:09:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	17 Nov 2020 20:21:34

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:09:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Nov 2020 20:21:34

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:09:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Nov 2020 20:21:34

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:09:28

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:49:23
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Nov 2020 07:14:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Nov 2020 07:14:01
Data point term sent to Coder	System	17 Nov 2020 20:22:59
User entered 'ASPIRIN'	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 20:22:32

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:09:28

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:49:25
User entered 'Yes (Y)'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 20:22:32
	(b) (4)	

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:09:28

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:49:26
User entered 'CARDIOVASCULAR PROHYLAXIS'	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 20:22:32

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:09:28

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:49:28
User entered '81'	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 20:22:32

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:09:28

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:49:30
User entered 'mg (mg)'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 20:22:32
	(b) (4)	

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:09:28

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:49:31
User entered empty.	Rosaidaliz Carreira (b) (4)	17 Nov 2020 20:22:32
	(b) (4)	

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:09:28

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:49:33
User entered 'once daily (QD)'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 20:22:32
	(b) (4)	

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:09:28

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:49:35
User entered empty.	Rosaidaliz Carreira (b) (4)	17 Nov 2020 20:22:32
	(b) (4)	

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:09:28

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:49:37
User entered 'Oral (ORAL)'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 20:22:32
	(b) (4)	

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:09:28

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:49:39
User entered empty.	Rosaidaliz Carreira (b) (4)	17 Nov 2020 20:22:32
	(b) (4)	

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:09:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:49:41
User entered '10 Nov 2020'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 20:22:32
	(b) (4)	

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:09:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:49:43
User entered '0'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 20:22:32
	(b) (4)	

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:09:28

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:49:45
User entered 'Yes (Y)'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 20:22:32
	(b) (4)	

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:49:46
User entered empty.	Rosaidaliz Carreira (b) (4)	17 Nov 2020 20:22:32
	(b) (4)	

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:09:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:49:49
User entered 'No (N)'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 20:22:32
	(b) (4)	

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:09:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Nov 2020 20:22:32

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:09:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Nov 2020 20:22:32

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:09:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Nov 2020 20:22:32

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:09:28

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:35
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:03:26
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC., ATC: ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC., ATC: ANESTHETICS FOR TOPICAL USE, PRODUCT: LIDOCAINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 10:05:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 10:05:41
Data point term sent to Coder	System	12 Apr 2021 16:45:23
Coding entries removed.	(b) (4), (b) (6)	12 Apr 2021 16:44:43
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 10:30:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 10:30:38
Data point term sent to Coder	System	07 Apr 2021 17:33:17
Coding entries removed.	Yulexis Amestoy (b) (4) (b) (4)	07 Apr 2021 17:32:48
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 13:31:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 13:31:43
Data point term sent to Coder	System	05 Mar 2021 14:35:48
DataPoint Un-verified.	Matthew Muniz (b) (4)	05 Mar 2021 14:34:54

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:09:28

[Name of Medication](#)

Audit	User	Time (GMT)
Coding entries removed.	Matthew Muniz (b) (4)	05 Mar 2021 14:34:54
User entered 'LIDOCAINE 2%' reason for change:	Matthew Muniz (b) (4)	05 Mar 2021 14:34:54
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 18:53:16
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Jan 2021 00:00:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Jan 2021 00:00:38
Data point term sent to Coder	System	25 Jan 2021 21:21:43
User entered 'Lidocaine'	Rosaidaliz Carreira (b) (4) (b) (4)	25 Jan 2021 21:20:48

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:09:28

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:35
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 18:53:16
User entered 'No (N)'	Rosaidaliz Carreira (b) (4)	25 Jan 2021 21:20:48

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:09:28

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:35
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 18:53:16
User entered 'Angioplasty Anesthetic'	Rosaidaliz Carreira (b) (4)	25 Jan 2021 21:20:48

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:09:28

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:35
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:03:29
User closed query 'Per DM CLR: Please provide the strength of this medication in the medication name, and consider recording the number of vial instead (e.g. dose=1; unit=vial). Review and amend as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 07:29:01
Query 'Per DM CLR: Please provide the strength of this medication in the medication name, and consider recording the number of vial instead (e.g. dose=1; unit=vial). Review and amend as appropriate.' answered with 'updated ' (Site from DM).	Matthew Muniz (b) (4)	05 Mar 2021 14:36:02
DataPoint Un-verified.	Matthew Muniz (b) (4)	05 Mar 2021 14:34:54
User entered '1' reason for change: Data Entry Error	Matthew Muniz (b) (4)	05 Mar 2021 14:34:54
User opened query 'Per DM CLR: Please provide the strength of this medication in the medication name, and consider recording the number of vial instead (e.g. dose=1; unit=vial). Review and amend as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 01:20:24
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 18:53:16
User entered '2 %'	Rosaidaliz Carreira (b) (4)	25 Jan 2021 21:20:48

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:09:28

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:35
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 18:53:16
User entered 'Other (OTHER)'	Rosaidaliz Carreira (b) (4)	25 Jan 2021 21:20:48

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:09:28

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:35
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:03:38
User entered 'vial' reason for change: Data Entry Error	Matthew Muniz (b) (4)	05 Mar 2021 14:35:42
DataPoint Un-verified.	Matthew Muniz (b) (4)	05 Mar 2021 14:34:54
User entered 'application' reason for change: Data Entry Error	Matthew Muniz (b) (4)	05 Mar 2021 14:34:54
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 18:53:16
User entered 'Percutaneous'	Rosaidaliz Carreira (b) (4)	25 Jan 2021 21:20:48
	(b) (4)	

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:09:28

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:35
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 18:53:16
User entered 'once (ONCE)'	Rosaidaliz Carreira (b) (4)	25 Jan 2021 21:20:48

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:09:28

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:35
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 18:53:16
User entered empty.	Rosaidaliz Carreira (b) (4)	25 Jan 2021 21:20:48
	(b) (4)	

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:09:28

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:35
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:03:38
User closed query 'Per CDM: As Topical is one of the listed choices in Route of administration, kindly consider to update this field as appropriate leaving the route of administration is other, specify field as blank. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 15:50:54
Query 'Per CDM: As Topical is one of the listed choices in Route of administration, kindly consider to update this field as appropriate leaving the route of administration is other, specify field as blank. Please review and reconcile.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 16:45:13
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 16:44:43
User entered 'Topical (TOPICAL)' reason for change: Data Entry Error		12 Apr 2021 16:44:43
User opened query 'Per CDM: As Topical is one of the listed choices in Route of administration, kindly consider to update this field as appropriate leaving the route of administration is other, specify field as blank. Please review and reconcile.' (Site from DM).		10 Apr 2021 08:15:52
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 18:53:16
User entered 'Other (OTHER)'	Rosaidaliz Carreira (b) (4)	25 Jan 2021 21:20:48
	(b) (4)	

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:09:28

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:35
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:03:38
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 16:44:43
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 05:52:24
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' answered with 'corrected' (Site from DM).	Yulexis Amestoy (b) (4)	07 Apr 2021 17:33:00
DataPoint Un-verified.	Yulexis Amestoy (b) (4)	07 Apr 2021 17:32:48
User entered 'Topical' reason for change: Data Entry Error	Yulexis Amestoy (b) (4)	07 Apr 2021 17:32:48
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 14:19:50
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 18:53:16
User entered 'Percutaneous'	Rosaidaliz Carreira (b) (4)	25 Jan 2021 21:20:48

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:09:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:35
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 18:53:16
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	25 Jan 2021 21:21:23
User entered '09 Nov 2020' reason for change: Data Entry Error	Rosaidaliz Carreira (b) (4)	25 Jan 2021 21:21:23
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	25 Jan 2021 21:20:48
User entered '09 Nov 2021'	Rosaidaliz Carreira (b) (4)	25 Jan 2021 21:20:48

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:09:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:35
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 18:53:16
User entered '0'	Rosaidaliz Carreira (b) (4)	25 Jan 2021 21:20:48

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:09:28

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:35
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 18:53:16
User entered 'No (N)'	Rosaidaliz Carreira (b) (4)	25 Jan 2021 21:20:48

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:09:28

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:35
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 18:53:16
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	25 Jan 2021 21:21:23
User entered '09 Nov 2020' reason for change: Data Entry Error	Rosaidaliz Carreira (b) (4)	25 Jan 2021 21:21:23
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	(b) (4)	25 Jan 2021 21:20:48
User entered empty.	Rosaidaliz Carreira (b) (4)	25 Jan 2021 21:20:48
	(b) (4)	

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:09:28

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:35
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 18:53:16
User entered 'No (N)'	Rosaidaliz Carreira (b) (4)	25 Jan 2021 21:20:48

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:09:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:35
User entered empty.	System	25 Jan 2021 21:20:48

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:09:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:35
User entered empty.	System	25 Jan 2021 21:20:48

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:09:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:35
User entered empty.	System	25 Jan 2021 21:20:48

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:09:28

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:37
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:21:51
Query 'Please provide source for Concomitant Medication, for CRA to verify. ' canceled (Site from CRA).	(b) (4), (b) (6)	24 Feb 2021 17:21:34
User opened query 'Please provide source for Concomitant Medication, for CRA to verify. ' (Site from CRA).	(b) (4), (b) (6)	22 Feb 2021 15:23:48
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)	10 Feb 2021 20:48:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Feb 2021 20:48:51
Data point term sent to Coder	System	10 Feb 2021 20:47:59
User entered 'TYLENOL'	Yulexis Amestoy (b) (4) (b) (4)	10 Feb 2021 20:47:58

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:09:28

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:37
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:21:51
User entered 'No (N)'	Yulexis Amestoy (b) (4)	10 Feb 2021 20:47:58

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:09:28

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:37
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:21:51
User entered 'PAIN AT INJECTION SITE'	Yulexis Amestoy (b) (4)	10 Feb 2021 20:47:58

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:09:28

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:37
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:21:51
User entered '1000'	Yulexis Amestoy (b) (4)	10 Feb 2021 20:47:58

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:09:28

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:37
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:21:51
User entered 'mg (mg)'	Yulexis Amestoy (b) (4)	10 Feb 2021 20:47:58
	(b) (4)	

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:09:28

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:37
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:21:51
User entered empty.	Yulexis Amestoy (b) (4)	10 Feb 2021 20:47:58

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:09:28

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:37
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:21:51
User entered 'once daily (QD)'	Yulexis Amestoy (b) (4)	10 Feb 2021 20:47:58

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:09:28

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:37
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:21:51
User entered empty.	Yulexis Amestoy (b) (4)	10 Feb 2021 20:47:58

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:09:28

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:37
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:21:51
User entered 'Oral (ORAL)'	Yulexis Amestoy (b) (4)	10 Feb 2021 20:47:58

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:09:28

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:37
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:21:51
User entered empty.	Yulexis Amestoy (b) (4)	10 Feb 2021 20:47:58

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:09:28

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:37
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:21:51
User entered '4 Feb 2021'	Yulexis Amestoy (b) (4)	10 Feb 2021 20:47:58

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:09:28

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:37
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:21:51
User entered '0'	Yulexis Amestoy (b) (4)	10 Feb 2021 20:47:58
	(b) (4)	

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:09:28

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:37
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:21:51
User entered 'No (N)'	Yulexis Amestoy (b) (4)	10 Feb 2021 20:47:58
	(b) (4)	

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:09:28

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:37
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:21:51
User entered '4 Feb 2021'	Yulexis Amestoy (b) (4)	10 Feb 2021 20:47:58
	(b) (4)	

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:09:28

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:37
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
User closed query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of PAIN AT INJECTION SITE in eDiary. Please note that this CM was given beyond day 7 and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRF and update this field to No. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 05:29:53
Query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of PAIN AT INJECTION SITE in eDiary. Please note that this CM was given beyond day 7 and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRF and update this field to No. Else, provide clarification.' answered with 'Captured within 7 days after vaccination on 03-Feb2021 OL-D29' (Site from DM).	Matthew Muniz (b) (4)	02 Mar 2021 14:32:21
User opened query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of PAIN AT INJECTION SITE in eDiary. Please note that this CM was given beyond day 7 and no AE has been recorded. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRF and update this field to No. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 11:24:25
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:21:51
User entered 'Yes (Y)'	Yulexis Amestoy (b) (4) (b) (4)	10 Feb 2021 20:47:58

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:09:28

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:37
User entered '1'	System	10 Feb 2021 20:47:58

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:09:28

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:37
User entered '1'	System	10 Feb 2021 20:47:58

US3352033

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:09:28

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:40:37
User entered '804 (804)'	System	10 Feb 2021 20:47:58

US3352033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:09:28

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:51:31
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
User closed query 'Please clarify , per source in medical record for AE on 05NOV2020 subject had Chest Xray and Transthoracic Echocardiogram 05NOV2020, please add these to Concomitant Procedures page.' (Site from CRA).	(b) (4), (b) (6)	13 Jan 2021 21:31:28
Query 'Please clarify , per source in medical record for AE on 05NOV2020 subject had Chest Xray and Transthoracic Echocardiogram 05NOV2020, please add these to Concomitant Procedures page.' answered with 'updated' (Site from CRA).	Matthew Muniz (b) (4)	11 Jan 2021 17:25:38
User opened query 'Please clarify , per source in medical record for AE on 05NOV2020 subject had Chest Xray and Transthoracic Echocardiogram 05NOV2020, please add these to Concomitant Procedures page.' (Site from CRA).	(b) (4), (b) (6)	11 Jan 2021 15:19:32
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:50:53
User entered 'Yes (Y)'	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 20:23:34

US3352033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:09:28

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:50:43
User entered '05 Nov 2020'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 20:24:44
	(b) (4)	

US3352033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:09:28

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:50:43
User entered 'TWO ANGIOPLASTY WITH STENT'	Rosaidaliz Carreira (b) (4) (b) (4)	17 Nov 2020 20:24:44

US3352033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:09:28

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:50:43
User entered 'Adverse Event (AE)'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 20:24:44
	(b) (4)	

US3352033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:09:28

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:50:43
User entered empty.	Rosaidaliz Carreira (b) (4)	17 Nov 2020 20:24:44
	(b) (4)	

US3352033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:09:28

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:34:57
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:50:43
User entered '09 Nov 2020'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 20:25:08

US3352033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:09:28

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:34:57
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:50:43
User entered 'TWO ANGIOPLASTY WITH STENT'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 20:25:08
	(b) (4)	

US3352033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:09:28

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:34:57
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:50:43
User entered 'Adverse Event (AE)'	Rosaidaliz Carreira (b) (4)	17 Nov 2020 20:25:08

US3352033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:09:28

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:34:57
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:50:43
User entered empty.	Rosaidaliz Carreira (b) (4)	17 Nov 2020 20:25:08

US3352033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:09:28

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:34:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 21:31:00
User entered '05 Nov 2020'	Matthew Muniz (b) (4)	11 Jan 2021 17:24:08

US3352033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:09:28

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:34:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 21:31:00
User entered 'chest xray'	Matthew Muniz (b) (4)	11 Jan 2021 17:24:08

US3352033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:09:28

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:34:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 21:31:00
User entered 'Adverse Event (AE)'	Matthew Muniz (b) (4)	11 Jan 2021 17:24:08

US3352033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:09:28

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:34:58
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 21:31:00
User entered empty.	Matthew Muniz (b) (4)	11 Jan 2021 17:24:08

US3352033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:09:28

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:35:02
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 21:31:00
User entered '05 Nov 2020'	Matthew Muniz (b) (4)	11 Jan 2021 17:25:31

US3352033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:09:28

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:35:02
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 21:31:00
User entered 'transthoracic echocardiogram'	Matthew Muniz (b) (4)	11 Jan 2021 17:25:31

US3352033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:09:28

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:35:02
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 21:31:00
User entered 'Adverse Event (AE)'	Matthew Muniz (b) (4)	11 Jan 2021 17:25:31

US3352033

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:09:28

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:35:02
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:55:02
DataPoint Verified.	(b) (4), (b) (6)	13 Jan 2021 21:31:00
User entered empty.	Matthew Muniz (b) (4)	11 Jan 2021 17:25:31

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'USA-US066-2020-MRNA-1273-P301000004'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

Serious

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'Yes (Y)'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

Death

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'No (N)'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'No (N)'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'Yes (Y)'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'No (N)'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'No (N)'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'No (N)'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'Howard'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'schwartz'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered '7265 SHeridan Street SUite 210'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'Pembroke Pines'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'FL'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered '33024'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:12:26
User entered 'US'	System	09 Nov 2020 18:08:18

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	26 Jan 2021 19:27:25
User entered '6'	System	21 Dec 2020 15:53:01
User entered '5'	System	08 Dec 2020 15:05:18
User entered '4'	System	23 Nov 2020 21:51:38
User entered '3'	System	18 Nov 2020 17:25:28
User entered '2'	System	13 Nov 2020 13:12:34
User entered '1'	System	09 Nov 2020 18:08:18

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'USA-US066-2020-MRNA-1273-P301000004'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

Serious

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'Yes (Y)'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

Death

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'No (N)'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'No (N)'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'Yes (Y)'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'No (N)'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'No (N)'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'No (N)'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'Howard'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'schwartz'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered '7265 SHeridan Street SUite 210'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'Pembroke Pines'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'FL'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered '33024'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:12:26
User entered 'US'	System	09 Nov 2020 18:08:18

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	26 Jan 2021 19:27:25
User entered '6'	System	21 Dec 2020 15:53:01
User entered '5'	System	08 Dec 2020 15:05:18
User entered '4'	System	23 Nov 2020 21:51:38
User entered '3'	System	18 Nov 2020 17:25:28
User entered '2'	System	13 Nov 2020 13:12:34
User entered '1'	System	09 Nov 2020 18:08:18

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:09:28

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
User entered '09/Nov/2020 18:08'	System	09 Nov 2020 18:08:18

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:09:28

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 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.		13 Nov 2020 13:12:26
User entered 'I'		09 Nov 2020 18:08:18

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'USA-US066-2020-MRNA-1273-P301000004'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

Serious

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'Yes (Y)'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

Death

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'No (N)'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'No (N)'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'Yes (Y)'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'No (N)'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'No (N)'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'No (N)'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'Howard'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'schwartz'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered '7265 SHeridan Street SUite 210'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'Pembroke Pines'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'FL'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered '33024'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:12:26
User entered 'US'	System	09 Nov 2020 18:08:18

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	26 Jan 2021 19:27:25
User entered '6'	System	21 Dec 2020 15:53:01
User entered '5'	System	08 Dec 2020 15:05:18
User entered '4'	System	23 Nov 2020 21:51:38
User entered '3'	System	18 Nov 2020 17:25:28
User entered '2'	System	13 Nov 2020 13:12:34
User entered '1'	System	09 Nov 2020 18:08:18

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:09:28

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
User entered '13/Nov/2020 08:12'	System	13 Nov 2020 13:12:34

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:09:28

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 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.		23 Nov 2020 21:51:20
User entered 'I'		13 Nov 2020 13:12:34

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'USA-US066-2020-MRNA-1273-P301000004'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

Serious

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'Yes (Y)'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

Death

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'No (N)'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'No (N)'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'Yes (Y)'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'No (N)'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'No (N)'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'No (N)'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'Howard'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'schwartz'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered '7265 SHeridan Street SUite 210'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'Pembroke Pines'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'FL'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered '33024'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:12:26
User entered 'US'	System	09 Nov 2020 18:08:18

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	26 Jan 2021 19:27:25
User entered '6'	System	21 Dec 2020 15:53:01
User entered '5'	System	08 Dec 2020 15:05:18
User entered '4'	System	23 Nov 2020 21:51:38
User entered '3'	System	18 Nov 2020 17:25:28
User entered '2'	System	13 Nov 2020 13:12:34
User entered '1'	System	09 Nov 2020 18:08:18

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:09:28

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
User entered '18/Nov/2020 12:25'	System	18 Nov 2020 17:25:28

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:09:28

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 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.		23 Nov 2020 21:51:20
User entered 'I'		18 Nov 2020 17:25:28

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'USA-US066-2020-MRNA-1273-P301000004'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

Serious

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'Yes (Y)'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

Death

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'No (N)'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'No (N)'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'Yes (Y)'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'No (N)'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'No (N)'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'No (N)'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'Howard'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'schwartz'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered '7265 SHeridan Street SUite 210'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'Pembroke Pines'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'FL'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered '33024'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:12:26
User entered 'US'	System	09 Nov 2020 18:08:18

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	26 Jan 2021 19:27:25
User entered '6'	System	21 Dec 2020 15:53:01
User entered '5'	System	08 Dec 2020 15:05:18
User entered '4'	System	23 Nov 2020 21:51:38
User entered '3'	System	18 Nov 2020 17:25:28
User entered '2'	System	13 Nov 2020 13:12:34
User entered '1'	System	09 Nov 2020 18:08:18

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:09:28

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
User entered '23/Nov/2020 16:51'	System	23 Nov 2020 21:51:38

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:09:28

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 19:57:06
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 15:05:10
DataPoint Verified.		03 Dec 2020 16:26:51
User entered 'I'		23 Nov 2020 21:51:38

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'USA-US066-2020-MRNA-1273-P301000004'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

Serious

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'Yes (Y)'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

Death

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'No (N)'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'No (N)'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'Yes (Y)'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'No (N)'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'No (N)'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'No (N)'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'Howard'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'schwartz'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered '7265 SHeridan Street SUite 210'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'Pembroke Pines'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'FL'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered '33024'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:12:26
User entered 'US'	System	09 Nov 2020 18:08:18

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	26 Jan 2021 19:27:25
User entered '6'	System	21 Dec 2020 15:53:01
User entered '5'	System	08 Dec 2020 15:05:18
User entered '4'	System	23 Nov 2020 21:51:38
User entered '3'	System	18 Nov 2020 17:25:28
User entered '2'	System	13 Nov 2020 13:12:34
User entered '1'	System	09 Nov 2020 18:08:18

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:09:28

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:07:29
User entered '08/Dec/2020 10:05'	System	08 Dec 2020 15:05:18

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:09:28

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 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:07:29
Reviewed for Safety.		21 Dec 2020 15:52:37
User entered 'I'		08 Dec 2020 15:05:18

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'USA-US066-2020-MRNA-1273-P301000004'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

Serious

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'Yes (Y)'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

Death

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'No (N)'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'No (N)'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'Yes (Y)'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'No (N)'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'No (N)'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'No (N)'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'Howard'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'schwartz'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered '7265 SHeridan Street SUite 210'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'Pembroke Pines'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'FL'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered '33024'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:12:26
User entered 'US'	System	09 Nov 2020 18:08:18

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	26 Jan 2021 19:27:25
User entered '6'	System	21 Dec 2020 15:53:01
User entered '5'	System	08 Dec 2020 15:05:18
User entered '4'	System	23 Nov 2020 21:51:38
User entered '3'	System	18 Nov 2020 17:25:28
User entered '2'	System	13 Nov 2020 13:12:34
User entered '1'	System	09 Nov 2020 18:08:18

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:09:28

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:07:29
User entered '21/Dec/2020 10:52'	System	21 Dec 2020 15:53:01

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:09:28

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 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:07:29
Reviewed for Safety.		26 Jan 2021 19:27:13
User entered 'I'		21 Dec 2020 15:53:01

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'USA-US066-2020-MRNA-1273-P301000004'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

Serious

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'Yes (Y)'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

Death

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'No (N)'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'No (N)'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'Yes (Y)'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'No (N)'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'No (N)'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'No (N)'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'Howard'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'schwartz'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered '7265 SHeridan Street SUite 210'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'Pembroke Pines'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered 'FL'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 18:08:12
User entered '33024'	System	09 Nov 2020 18:07:52

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 16:26:51
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:12:26
User entered 'US'	System	09 Nov 2020 18:08:18

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:09:28

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	26 Jan 2021 19:27:25
User entered '6'	System	21 Dec 2020 15:53:01
User entered '5'	System	08 Dec 2020 15:05:18
User entered '4'	System	23 Nov 2020 21:51:38
User entered '3'	System	18 Nov 2020 17:25:28
User entered '2'	System	13 Nov 2020 13:12:34
User entered '1'	System	09 Nov 2020 18:08:18

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 17:09:28

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Howard schwartz (b) (4)	26 Apr 2021 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:07:29
User entered '26/Jan/2021 14:27'	System	26 Jan 2021 19:27:25

US3352033

Folder: SAE USA-US066-2020-MRNA-1273-P301000004

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 17:09:28

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 19:57:06
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:07:29
User entered 'I'	(b) (4), (b) (6)	26 Jan 2021 19:27:25