

US3392133 (Prod: Benchmark Research - Metairie - PPDS)

Generated By: KC Joubran

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All time stamps listed in this document are displayed in GMT

US3392133

Form: Participant Creation

Data signed: (b) (4) 28 Apr 2021 22:17:32

Generated On: 09 Jun 2021 17:26:26

Participant ID

US3392133

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

US3392133

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 03:13:27

Generated On: 09 Jun 2021 17:26:26

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	01 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	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 20 Feb 2021 03:13:27

Generated On: 09 Jun 2021 17:26:26

Date of Birth (MMM yyyy)	(b) (6) 1975
Age	45
Age Units	YEARS
Age (Derived)	45
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

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 20 Feb 2021 03:13:27

Generated On: 09 Jun 2021 17:26:26

Date of Informed Consent (<i>dd MMM yyyy</i>)	1 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input checked="" 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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 20 Feb 2021 03:13:27

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 20 Feb 2021 03:13:27

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Were any significant conditions reported?

Yes ☐

No ☒

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 20 Feb 2021 03:13:27

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Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	1 SEP 2020
Time of assessment (00:00-23:59)	08:54 (24 HR)
Vital Signs Date and Time (derived)	1 SEP 2020 08:54
Height (xxx.x)	73.0 in
Weight (xxx.x)	200.0 lb
BMI (xxx.x)	26.44199 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input 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) 20 Feb 2021 03:13:27

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

1 SEP 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) 20 Feb 2021 03:13:27

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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

ONLINE MARKETING/WORKS
IN OFFICE A FEW HOURS/DAY

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) 20 Feb 2021 03:13:27

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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) 20 Feb 2021 02:52:33

Generated On: 09 Jun 2021 17:26:26

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	1 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	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 20 Feb 2021 02:52:33

Generated On: 09 Jun 2021 17:26:26

What was the date of randomization? (dd MMM yyyy) 01 SEP 2020

What was the participant's randomization number? 110573

In what Cohort was the participant enrolled?
 >=18 and <65 years and not at risk ☒
 >=18 and <65 years and at risk ☐
 >=65 years ☐

If participant is considered at risk, please check all that apply (If any are checked as Yes, please ensure the actual condition is recorded on the Medical History form)

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma) Yes ☐ No ☒

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension) Yes ☐ No ☒

Severe obesity (body mass index > or = 40kg/m2) Yes ☐ No ☒

Diabetes (Type I, Type 2, or gestational) Yes ☐ No ☒

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 20 Feb 2021 02:52:33

Generated On: 09 Jun 2021 17:26:26

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 20 Feb 2021 02:52:33

Generated On: 09 Jun 2021 17:26:26

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	1 SEP 2020
Time of assessment (00:00-23:59)	08:54 (24 HR)
Vital Signs Date and Time (derived)	1 SEP 2020 08:54
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	90 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	149 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 20 Feb 2021 02:52:33

Generated On: 09 Jun 2021 17:26:26

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	1 SEP 2020
Time of assessment (00:00-23:59)	10:53 (24 HR)
Vital Signs Date and Time (derived)	1 SEP 2020 10:53
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	82 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)	97 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 02:52:33

Generated On: 09 Jun 2021 17:26:26

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

1 SEP 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 20 Feb 2021 02:52:33

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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) 1 SEP 2020

What was the treatment time? (00:00-23:59) 10:21 (24 HR)

Treatment Date and Time (derived) 1 SEP 2020 10:21

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) 20 Feb 2021 02:52:33

Generated On: 09 Jun 2021 17:26:26

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	1 SEP 2020
Collection time (00:00-23:59)	09:17 (24 HR)
Collection date and time (derived)	1 SEP 2020 09:17

US3392133

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 20 Feb 2021 02:52:33

Generated On: 09 Jun 2021 17:26:26

Collection date (dd MMM yyyy)			1 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:12	1 SEP 2020 09:12
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 02:52:33

Generated On: 09 Jun 2021 17:26:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

01 SEP 2020 10:54

PC Open Date & Time

01 SEP 2020 10:41

PC Close Date & Time

01 SEP 2020 13:11

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

PC Time Stamp	01 SEP 2020 22:10
PC Open Date & Time	01 SEP 2020 14:06
PC Close Date & Time	02 SEP 2020 11:59

US3392133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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

02 SEP 2020 18:35

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3392133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

03 SEP 2020 12:18

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3392133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 12:01

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3392133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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

05 SEP 2020 12:40

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3392133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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

06 SEP 2020 19:51

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3392133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☒

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 SEP 2020 13:00

PC Open Date & Time 07 SEP 2020 12:00

PC Close Date & Time 08 SEP 2020 11:59

US3392133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 SEP 2020 10:54

PC Open Date & Time

01 SEP 2020 10:41

PC Close Date & Time

01 SEP 2020 13:11

US3392133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 SEP 2020 22:10

PC Open Date & Time

01 SEP 2020 14:06

PC Close Date & Time

02 SEP 2020 11:59

US3392133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 SEP 2020 18:35

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3392133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 12:19

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3392133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 SEP 2020 12:01

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3392133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 SEP 2020 12:40

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3392133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 SEP 2020 19:51

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3392133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 SEP 2020 13:00

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:26:26

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

No ☒

Yes ☐

PC Time stamp	01 SEP 2020 10:55
PC Open Date & Time	01 SEP 2020 10:41
PC Close Date & Time	01 SEP 2020 13:11

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:26:26

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

No ☒

Yes ☐

PC Time stamp	01 SEP 2020 22:10
PC Open Date & Time	01 SEP 2020 14:06
PC Close Date & Time	02 SEP 2020 11:59

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:26:26

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 18:36
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:26:26

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 12:19
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:26:26

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 12:01
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:26:26

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 12:41
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

49 of 1838

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:26:26

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 19:51
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:26:26

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 13:01
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3392133

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 01:06:03

Generated On: 09 Jun 2021 17:26:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3392133

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 01:06:03

Generated On: 09 Jun 2021 17:26:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392133

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 02:32:42

Generated On: 09 Jun 2021 17:26:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3392133

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 02:32:41

Generated On: 09 Jun 2021 17:26:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392133

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 02:13:15

Generated On: 09 Jun 2021 17:26:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3392133

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 02:13:15

Generated On: 09 Jun 2021 17:26:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392133

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 04:40:45

Generated On: 09 Jun 2021 17:26:26

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 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

US3392133

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 21 Feb 2021 04:40:45

Generated On: 09 Jun 2021 17:26:26

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 SEP 2020
Time of assessment (00:00-23:59)	08:45 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 08:45
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	89 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	147 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3392133

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 21 Feb 2021 04:40:45

Generated On: 09 Jun 2021 17:26:26

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 SEP 2020
Time of assessment (00:00-23:59)	09:59 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 09:59
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	89 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	152 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	99 mmHg
Diastolic Blood Pressure units	MMHG

US3392133

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 04:40:45

Generated On: 09 Jun 2021 17:26:26

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 SEP 2020

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

US3392133

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 21 Feb 2021 04:40:45

Generated On: 09 Jun 2021 17:26:26

Was study treatment given? Yes ☒
No ☐

If No, reason not given

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 28 SEP 2020

What was the treatment time? (00:00-23:59) 09:28 (24 HR)

Treatment Date and Time (derived) 28 SEP 2020 09:28

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

US3392133

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 04:40:45

Generated On: 09 Jun 2021 17:26:26

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	28 SEP 2020
Collection time (00:00-23:59)	08:55 (24 HR)
Collection date and time (derived)	28 SEP 2020 08:55

US3392133

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 21 Feb 2021 04:40:45

Generated On: 09 Jun 2021 17:26:26

Collection date (dd MMM yyyy)			28 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:52	28 SEP 2020 08:52
Nasopharyngeal Swab 2	No		

US3392133

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 04:40:45

Generated On: 09 Jun 2021 17:26:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

28 SEP 2020 09:50

PC Open Date & Time

28 SEP 2020 09:48

PC Close Date & Time

28 SEP 2020 12:18

US3392133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.3 °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	28 SEP 2020 13:13
PC Open Date & Time	28 SEP 2020 13:13
PC Close Date & Time	29 SEP 2020 11:59

US3392133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	102.1 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	29 SEP 2020 14:19
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3392133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.1 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

30 SEP 2020 12:40

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3392133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3392133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3392133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3392133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 SEP 2020 09:51

PC Open Date & Time

28 SEP 2020 09:48

PC Close Date & Time

28 SEP 2020 12:18

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 SEP 2020 13:14

PC Open Date & Time

28 SEP 2020 13:13

PC Close Date & Time

29 SEP 2020 11:59

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 SEP 2020 14:20

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 SEP 2020 12:40

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 5

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 6

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 7

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:26:26

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

No ☒

Yes ☐

PC Time stamp	28 SEP 2020 09:51
PC Open Date & Time	28 SEP 2020 09:48
PC Close Date & Time	28 SEP 2020 12:18

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:26:26

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

No ☒

Yes ☐

PC Time stamp	28 SEP 2020 13:14
PC Open Date & Time	28 SEP 2020 13:13
PC Close Date & Time	29 SEP 2020 11:59

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☒

Prevents daily activity and
requires medical attention ☐

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

No ☐

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EAB) (1725)

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:26:26

	Yes <input type="radio"/>
PC Time stamp	29 SEP 2020 14:21
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☒

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:26:26

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 12:40
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 4

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:26:26

Yes ☐

PC Time stamp

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 5

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:26:26

Yes ☐

PC Time stamp

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 6

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:26:26

Yes ☐

PC Time stamp

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 7

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:26:26

Yes ☐

PC Time stamp

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3392133

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 01:56:50

Generated On: 09 Jun 2021 17:26:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3392133

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 01:56:50

Generated On: 09 Jun 2021 17:26:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392133

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 01:40:36

Generated On: 09 Jun 2021 17:26:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3392133

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 01:40:36

Generated On: 09 Jun 2021 17:26:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392133

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 01:23:14

Generated On: 09 Jun 2021 17:26:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3392133

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 01:23:14

Generated On: 09 Jun 2021 17:26:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392133

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 05:22:42

Generated On: 09 Jun 2021 17:26:26

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 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

US3392133

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 21 Feb 2021 05:22:42

Generated On: 09 Jun 2021 17:26:26

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3392133

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 05:22:42

Generated On: 09 Jun 2021 17:26:26

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3392133

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 05:22:42

Generated On: 09 Jun 2021 17:26:26

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 OCT 2020

Collection time (00:00-23:59)

08:11 (24 HR)

Collection date and time (derived)

23 OCT 2020 08:11

US3392133

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 05:22:42

Generated On: 09 Jun 2021 17:26:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

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

Date and time of submission

Patient Cloud Open Date & Time

01 NOV 2020 00:01

Patient Cloud Close Date & Time

05 NOV 2020 23:59

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

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

Date and time of submission

Patient Cloud Open Date & Time

08 NOV 2020 00:01

Patient Cloud Close Date & Time

12 NOV 2020 23:59

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

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

Date and time of submission

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 82

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 NOV 2020 16:15:53

Patient Cloud Open Date & Time

19 NOV 2020 00:01

Patient Cloud Close Date & Time

23 NOV 2020 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 89

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 NOV 2020 06:49:31

Patient Cloud Open Date & Time

26 NOV 2020 00:01

Patient Cloud Close Date & Time

30 NOV 2020 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 DEC 2020 06:45:35
Patient Cloud Open Date & Time	03 DEC 2020 00:01
Patient Cloud Close Date & Time	07 DEC 2020 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 DEC 2020 20:33:25

Patient Cloud Open Date & Time

10 DEC 2020 00:01

Patient Cloud Close Date & Time

14 DEC 2020 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 DEC 2020 07:38:12

Patient Cloud Open Date & Time

17 DEC 2020 00:01

Patient Cloud Close Date & Time

21 DEC 2020 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 117

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

Patient Cloud Open Date & Time	24 DEC 2020 00:01
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Patient Cloud Close Date & Time	28 DEC 2020 23:59
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US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 DEC 2020 00:04:37

Patient Cloud Open Date & Time

31 DEC 2020 00:01

Patient Cloud Close Date & Time

04 JAN 2021 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 JAN 2021 04:00:27

Patient Cloud Open Date & Time

07 JAN 2021 00:01

Patient Cloud Close Date & Time

11 JAN 2021 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 JAN 2021 08:33:08

Patient Cloud Open Date & Time

14 JAN 2021 00:01

Patient Cloud Close Date & Time

18 JAN 2021 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 JAN 2021 00:25:01

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 JAN 2021 12:01:01

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 FEB 2021 19:01:25
Patient Cloud Open Date & Time	04 FEB 2021 00:01
Patient Cloud Close Date & Time	08 FEB 2021 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 FEB 2021 17:47:27

Patient Cloud Open Date & Time

11 FEB 2021 00:01

Patient Cloud Close Date & Time

15 FEB 2021 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 FEB 2021 15:21:57

Patient Cloud Open Date & Time

18 FEB 2021 00:01

Patient Cloud Close Date & Time

22 FEB 2021 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 FEB 2021 06:40:17

Patient Cloud Open Date & Time

25 FEB 2021 00:01

Patient Cloud Close Date & Time

01 MAR 2021 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 MAR 2021 14:43:17
Patient Cloud Open Date & Time	04 MAR 2021 00:01
Patient Cloud Close Date & Time	08 MAR 2021 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 MAR 2021 00:01
Patient Cloud Close Date & Time	15 MAR 2021 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	18 MAR 2021 08:56:51
Patient Cloud Open Date & Time	18 MAR 2021 00:01
Patient Cloud Close Date & Time	22 MAR 2021 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 MAR 2021 10:56:03

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 APR 2021 09:14:58

Patient Cloud Open Date & Time

01 APR 2021 00:01

Patient Cloud Close Date & Time

05 APR 2021 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 APR 2021 13:13:06

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 APR 2021 08:26:31

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 APR 2021 14:02:43

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 APR 2021 09:24:58

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 250

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

[Patient Cloud Open Date & Time](#)

06 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 257

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

[Patient Cloud Open Date & Time](#)

13 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 271

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

[Patient Cloud Open Date & Time](#)

27 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 278

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 285

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 JUN 2021 00:01
Patient Cloud Close Date & Time	14 JUN 2021 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 292

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

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

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

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

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

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

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

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

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 299

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	24 JUN 2021 00:01
Patient Cloud Close Date & Time	28 JUN 2021 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 306

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

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

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

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

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

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

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	01 JUL 2021 00:01
Patient Cloud Close Date & Time	05 JUL 2021 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 313

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

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

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

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

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

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

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 ☐

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

[Patient Cloud Open Date & Time](#)

08 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 327

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

[Patient Cloud Open Date & Time](#)

22 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

[Patient Cloud Open Date & Time](#)

05 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

Patient Cloud Open Date & Time	12 AUG 2021 00:01
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Patient Cloud Close Date & Time	16 AUG 2021 23:59
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US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

Patient Cloud Open Date & Time	19 AUG 2021 00:01
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Patient Cloud Close Date & Time	23 AUG 2021 23:59
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US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 362

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

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

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

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

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

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

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

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

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

Patient Cloud Open Date & Time	26 AUG 2021 00:01
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Patient Cloud Close Date & Time	30 AUG 2021 23:59
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US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

[Patient Cloud Open Date & Time](#)

02 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 376

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

[Patient Cloud Open Date & Time](#)

09 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

[Patient Cloud Open Date & Time](#)

23 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	30 SEP 2021 00:01
Patient Cloud Close Date & Time	04 OCT 2021 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

[Patient Cloud Open Date & Time](#)

07 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 411

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 418

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 425

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

[Patient Cloud Open Date & Time](#)

28 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

[Patient Cloud Open Date & Time](#)

04 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 439

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 NOV 2021 00:01
Patient Cloud Close Date & Time	15 NOV 2021 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	18 NOV 2021 00:01
Patient Cloud Close Date & Time	22 NOV 2021 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

[Patient Cloud Open Date & Time](#)

25 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

[Patient Cloud Open Date & Time](#)

02 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2021 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 467

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

[Patient Cloud Open Date & Time](#)

09 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 474

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

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

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

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

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

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

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

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

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 481

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

Patient Cloud Open Date & Time	23 DEC 2021 00:01
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Patient Cloud Close Date & Time	27 DEC 2021 23:59
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US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 488

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	30 DEC 2021 00:01
Patient Cloud Close Date & Time	03 JAN 2022 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 495

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

[Patient Cloud Open Date & Time](#)

06 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 502

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

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

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

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

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

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

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 ☐

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

[Patient Cloud Open Date & Time](#)

20 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

[Patient Cloud Open Date & Time](#)

27 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JAN 2022 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

[Patient Cloud Open Date & Time](#)

03 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

[Patient Cloud Open Date & Time](#)

10 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 537

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

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

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

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

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

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

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

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

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 FEB 2022 00:01
Patient Cloud Close Date & Time	21 FEB 2022 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

[Patient Cloud Open Date & Time](#)

24 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 551

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

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

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

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

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

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

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

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

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

[Patient Cloud Open Date & Time](#)

03 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 558

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

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

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

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

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

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

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

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

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 MAR 2022 00:01
Patient Cloud Close Date & Time	14 MAR 2022 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 MAR 2022 00:01
Patient Cloud Close Date & Time	21 MAR 2022 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 572

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

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

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

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

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

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

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 ☐

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

[Patient Cloud Open Date & Time](#)

24 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 579

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

[Patient Cloud Open Date & Time](#)

31 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

[Patient Cloud Open Date & Time](#)

07 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 593

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 APR 2022 00:01
Patient Cloud Close Date & Time	25 APR 2022 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 607

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

[Patient Cloud Open Date & Time](#)

28 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 614

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

[Patient Cloud Open Date & Time](#)

12 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 635

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

[Patient Cloud Open Date & Time](#)

02 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 649

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 656

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

[Patient Cloud Open Date & Time](#)

16 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 663

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

[Patient Cloud Open Date & Time](#)

23 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

[Patient Cloud Open Date & Time](#)

07 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 684

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

[Patient Cloud Open Date & Time](#)

14 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2022 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 JUL 2022 00:01
Patient Cloud Close Date & Time	25 JUL 2022 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 698

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

[Patient Cloud Open Date & Time](#)

04 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 712

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

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

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

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

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

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

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 ☐

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

[Patient Cloud Open Date & Time](#)

18 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

Patient Cloud Open Date & Time	25 AUG 2022 00:01
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Patient Cloud Close Date & Time	29 AUG 2022 23:59
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US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

[Patient Cloud Open Date & Time](#)

01 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

[Patient Cloud Open Date & Time](#)

08 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 747

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 754

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

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

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

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

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

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

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 761

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 768

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

[Patient Cloud Open Date & Time](#)

06 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2022 23:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

Patient Cloud Open Date & Time	20 OCT 2022 00:01
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Patient Cloud Close Date & Time	24 OCT 2022 23:59
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US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

Date and time of submission

Patient Cloud Open Date & Time	27 OCT 2022 00:01
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Patient Cloud Close Date & Time	31 OCT 2022 23:59
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US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

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

[Patient Cloud Open Date & Time](#)

03 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2022 23:59

US3392133

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:26:26

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		02 MAR 2021 13:34:17

US3392133

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 08 Mar 2021 22:56:43

Generated On: 09 Jun 2021 17:26:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3392133

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 22:56:43

Generated On: 09 Jun 2021 17:26:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392133

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 22:17:32

Generated On: 09 Jun 2021 17:26:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3392133

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 22:17:32

Generated On: 09 Jun 2021 17:26:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392133

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 22:17:33

Generated On: 09 Jun 2021 17:26:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3392133

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 22:17:32

Generated On: 09 Jun 2021 17:26:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392133

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 22:17:33

Generated On: 09 Jun 2021 17:26:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3392133

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 22:17:33

Generated On: 09 Jun 2021 17:26:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392133

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 22:17:33

Generated On: 09 Jun 2021 17:26:26

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

Visit date (dd MMM yyyy)	24 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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US3392133

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 22:17:33

Generated On: 09 Jun 2021 17:26:26

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3392133

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 22:17:33

Generated On: 09 Jun 2021 17:26:26

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3392133

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 22:17:33

Generated On: 09 Jun 2021 17:26:26

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	24 MAR 2021
Collection time (00:00-23:59)	15:22 (24 HR)
Collection date and time (derived)	24 MAR 2021 15:22

US3392133

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 22:17:33

Generated On: 09 Jun 2021 17:26:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392133

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 22:17:33

Generated On: 09 Jun 2021 17:26:26

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3392133

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 22:17:33

Generated On: 09 Jun 2021 17:26:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3392133

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:26

Was Contact Attempted? Yes ☐
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3392133

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:26

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3392133

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:26:26

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input type="checkbox"/>
	Safety Call <input type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

US3392133

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:26:26

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3392133

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

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 22:17:32

Generated On: 09 Jun 2021 17:26:26

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

Visit date (dd MMM yyyy)	25 JAN 2021
--------------------------	-------------

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

Folder OID	UNBLND_DECIDE
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US3392133

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

Form: Unblinding

Data signed: (b) (4) 28 Apr 2021 22:17:32

Generated On: 09 Jun 2021 17:26:26

Date of updated informed consent (dd MMM yyyy) 25 JAN 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (dd MMM yyyy) 25 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3392133

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 22:17:32

Generated On: 09 Jun 2021 17:26:26

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

25 JAN 2021

Collection time (00:00-23:59)

12:27 (24 HR)

Collection date and time (derived)

25 JAN 2021 12:27

US3392133

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 28 Apr 2021 22:17:32

Generated On: 09 Jun 2021 17:26:26

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

Collection date (dd MMM yyyy)	25 JAN 2021
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Collection time (00:00 - 23:59)	12:29
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Collection Date and Time (derived)	25 JAN 2021 12:29
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US3392133

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 28 Apr 2021 22:06:14

Generated On: 09 Jun 2021 17:26:26

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3392133

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 22:06:14

Generated On: 09 Jun 2021 17:26:26

AEID	USA-US119-2021-MRNA-1273-P30 1000008
Adverse event	ATRIAL FLUTTER
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)	09 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	12 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	09 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	12 MAR 2021
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) 28 Apr 2021 22:06:14

Generated On: 09 Jun 2021 17:26:26

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

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US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 29 Apr 2021 20:06:03

Generated On: 09 Jun 2021 17:26:26

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

Yes ☒

No ☐

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

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 29 Apr 2021 20:06:03

Generated On: 09 Jun 2021 17:26:26

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication VACCINE-INDUCED FEVER

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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US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 29 Apr 2021 20:06:03

Generated On: 09 Jun 2021 17:26:26

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		29 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 30 SEP 2020		
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input 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"/>

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 29 Apr 2021 20:06:03

Generated On: 09 Jun 2021 17:26:26

Name of Medication APIXABAN

Prophylaxis Yes ☐
No ☒

Indication ATRIAL FLUTTER

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 29 Apr 2021 20:06:03

Generated On: 09 Jun 2021 17:26:26

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	12 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 29 Apr 2021 20:06:03

Generated On: 09 Jun 2021 17:26:26

Name of Medication DIGOXIN

Prophylaxis Yes ☐
No ☒

Indication ATRIAL FLUTTER

Dose per administration 0.25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 29 Apr 2021 20:06:03

Generated On: 09 Jun 2021 17:26:26

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	12 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 29 Apr 2021 20:06:03

Generated On: 09 Jun 2021 17:26:26

Name of Medication FUROSEMIDE

Prophylaxis Yes ☐
No ☒

Indication ATRIAL FLUTTER

Dose per administration 20

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) 29 Apr 2021 20:06:03

Generated On: 09 Jun 2021 17:26:26

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	12 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 29 Apr 2021 20:06:03

Generated On: 09 Jun 2021 17:26:26

Name of Medication METOPROLOL

Prophylaxis Yes ☐
No ☒

Indication ATRIAL FLUTTER

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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) 29 Apr 2021 20:06:03

Generated On: 09 Jun 2021 17:26:26

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	12 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 29 Apr 2021 20:06:03

Generated On: 09 Jun 2021 17:26:26

Name of Medication METOPROLOL

Prophylaxis Yes ☐
No ☒

Indication ATRIAL FLUTTER

Dose per administration 25

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 (6)

Data signed: (b) (4) 29 Apr 2021 20:06:03

Generated On: 09 Jun 2021 17:26:26

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	12 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 29 Apr 2021 20:06:03

Generated On: 09 Jun 2021 17:26:26

Name of Medication SACUBITRIL-VALSARTAN

Prophylaxis Yes ☐
No ☒

Indication ATRILA FLUTTER

Dose per administration 24-26

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)

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 29 Apr 2021 20:06:03

Generated On: 09 Jun 2021 17:26:26

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	12 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3392133

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 29 Apr 2021 20:06:03

Generated On: 09 Jun 2021 17:26:26

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3392133

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:26:26

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

US3392133

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:26:26

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

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

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3392133

Folder: SAE USA-US119-2021-MRNA-1273-P301000008

Form: Safety Report Form

Data signed: (b) (4) 29 Apr 2021 20:06:03

Generated On: 09 Jun 2021 17:26:26

SAEID	USA-US119-2021-MRNA-1273-P301000008
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	MICHAEL
Investigator's Last Name	COTUGNO
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3392133

Folder: SAE USA-US119-2021-MRNA-1273-P301000008

Form: Safety Report Form (1)

Data signed: (b) (4) 29 Apr 2021 20:06:03

Generated On: 09 Jun 2021 17:26:26

SAEID	USA-US119-2021-MRNA-1273-P301000008
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	MICHAEL
Investigator's Last Name	COTUGNO
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	19/MAR/2021 12:09
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3392133

Folder: SAE USA-US119-2021-MRNA-1273-P301000008

Form: Safety Report Form (2)

Data signed: (b) (4) 29 Apr 2021 20:06:03

Generated On: 09 Jun 2021 17:26:26

SAEID	USA-US119-2021-MRNA-1273-P301000008
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	MICHAEL
Investigator's Last Name	COTUGNO
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	30/MAR/2021 09:34
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

US3392133

Folder: SAE USA-US119-2021-MRNA-1273-P301000008

Form: Safety Report Form (3)

Data signed: (b) (4) 29 Apr 2021 20:06:03

Generated On: 09 Jun 2021 17:26:26

SAEID	USA-US119-2021-MRNA-1273-P301000008
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	MICHAEL
Investigator's Last Name	COTUGNO
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	29/APR/2021 08:21
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3392133 (Prod: Benchmark Research - Metairie - PPDS)

US3392133

Form: Participant Creation

Generated On: 09 Jun 2021 17:26:26

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 19:01:33
User entered 'US3392133'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 14:00:11

US3392133

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:26:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:46:11
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:13:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:14:09
User entered 'Yes (Y)'	Brandon Illickal (b) (4)	01 Sep 2020 14:35:39

US3392133

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:26:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:46:11
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:13:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:14:09
User entered '01 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 14:00:12

US3392133

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:26:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:46:11
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:13:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:14:09
User entered 'Clinic (Clinic)'	Brandon Illickal (b) (4)	01 Sep 2020 14:35:39

US3392133

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:26:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:46:11
User entered 'SCRN'	System	01 Sep 2020 14:35:39

US3392133

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:26:26

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:46:11
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:13:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:16:44
User entered (b) (6) 1975'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 14:00:13

US3392133

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:26:26

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:46:11
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:13:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:16:44
User entered '45'	Brandon Illickal (b) (4)	01 Sep 2020 14:37:35

US3392133

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:26:26

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:46:11
User entered 'YEARS'	System	01 Sep 2020 14:37:35

US3392133

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:26:26

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:46:11
User entered '45'	System	01 Sep 2020 14:37:51

US3392133

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:26:26

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:46:11
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:13:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:16:44
User entered 'Male (M)' reason for change: Data Entry Error	Brandon Illickal (b) (4)	01 Sep 2020 14:38:58
User entered 'Female (F)'	Brandon Illickal (b) (4)	01 Sep 2020 14:37:35

US3392133

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:26:26

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:46:11
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:13:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:16:44
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Brandon Illickal (b) (4)	01 Sep 2020 14:37:35

US3392133

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:26:26

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:46:11
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:13:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:16:44
User entered 'I'	Brandon Illickal (b) (4)	01 Sep 2020 14:37:35

US3392133

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:26:26

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:46:11
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:13:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:16:44
User entered '0'	Brandon Illickal (b) (4)	01 Sep 2020 14:37:35

US3392133

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:26:26

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:46:11
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:13:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:16:44
User entered '0'	Brandon Illickal (b) (4)	01 Sep 2020 14:37:35

US3392133

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:26:26

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:46:11
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:13:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:16:44
User entered '0'	Brandon Illickal (b) (4)	01 Sep 2020 14:37:35

US3392133

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:26:26

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:46:11
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:13:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:16:44
User entered '0'	Brandon Illickal (b) (4)	01 Sep 2020 14:37:35

US3392133

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:26:26

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:46:11
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:13:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:16:44
User entered '0'	Brandon Illickal (b) (4)	01 Sep 2020 14:37:35

US3392133

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:26:26

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:46:11
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:13:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:16:44
User entered empty.	Brandon Illickal (b) (4)	01 Sep 2020 14:37:35

US3392133

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:26:26

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:46:11
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:13:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:16:44
User entered '0'	Brandon Illickal (b) (4)	01 Sep 2020 14:37:35

US3392133

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:26:26

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:46:11
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:13:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:16:44
User entered '0'	Brandon Illickal (b) (4)	01 Sep 2020 14:37:35

US3392133

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:26:26

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:46:11
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:13:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:16:55
User entered '1 Sep 2020'	Brandon Illickal (b) (4)	01 Sep 2020 14:37:51

US3392133

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:26:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:46:11
User entered 'Sep 2020'	System	01 Sep 2020 14:37:51

US3392133

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:26:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:46:11
User entered '2020'	System	01 Sep 2020 14:37:51

US3392133

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:26:26

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:46:11
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:13:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:16:55
User entered 'Amendment 3 (3)'	Brandon Illickal (b) (4)	01 Sep 2020 14:37:51

US3392133

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:26:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:46:11
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:13:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:16:55
User entered 'Yes (Y)'	Brandon Illickal (b) (4)	01 Sep 2020 14:37:51

US3392133

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:26:26

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:46:11
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:13:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:16:55
User entered empty.	Brandon Illickal (b) (4)	01 Sep 2020 14:37:51

US3392133

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:26:26

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:46:11
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:13:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:16:55
User entered empty.	Brandon Illickal (b) (4)	01 Sep 2020 14:37:51

US3392133

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:26:26

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:46:11
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:13:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:16:55
User entered 'No (N)'	Brandon Illickal (b) (4)	01 Sep 2020 14:37:51

US3392133

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:26:26

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:46:11
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:13:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:16:55
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 14:00:12

US3392133

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:26:26

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:46:11
User entered 'I'	System	01 Sep 2020 14:37:51

US3392133

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:26:26

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:46:11
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:13:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:17:04
User entered 'Yes (Y)'	Brandon Illickal (b) (4)	01 Sep 2020 14:37:40

US3392133

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:26:26

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:46:11
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:13:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:17:11
User entered 'No (N)'	Brandon Illickal (b) (4)	01 Sep 2020 14:37:56

US3392133

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:46:11
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:13:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:18:49
User entered 'Yes (Y)'	Brandon Illickal (b) (4)	01 Sep 2020 14:38:40

US3392133

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:46:11
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:13:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:18:49
User entered '1 Sep 2020'	Brandon Illickal (b) (4)	01 Sep 2020 14:38:40

US3392133

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:26

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:46:11
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:13:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:18:49
User entered '08:54'	Brandon Illickal (b) (4)	01 Sep 2020 14:38:40

US3392133

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:26

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:46:11
User entered '1 Sep 2020 08:54'	System	01 Sep 2020 14:38:40

US3392133

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:26

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:46:11
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:13:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:18:49
User entered '73.0' in	Brandon Illickal (b) (4)	01 Sep 2020 14:38:40
DataPoint set to visible.	System	01 Sep 2020 14:37:51

US3392133

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:26

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:46:11
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:13:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:18:49
User entered '200.0' lb	Brandon Illickal (b) (4)	01 Sep 2020 14:38:40
DataPoint set to visible.	System	01 Sep 2020 14:37:51

US3392133

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:26

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:46:11
User entered '26.44199'	System	01 Sep 2020 14:38:40
DataPoint set to visible.	System	01 Sep 2020 14:37:51

US3392133

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:26

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:46:11
User entered 'kg/m2'	System	01 Sep 2020 14:38:40
DataPoint set to visible.	System	01 Sep 2020 14:37:51

US3392133

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:46:11
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:13:28
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 15:18:49
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 17:50:08
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly. ' answered with 'updated' (Site from DM).	Brandon Illickal (b) (4)	29 Sep 2020 18:15:57
User entered missing code ND - Not Done; reason for change Data Entry Error	Brandon Illickal (b) (4)	29 Sep 2020 18:15:51
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 18:37:37
User entered '98.5' F	Brandon Illickal (b) (4)	01 Sep 2020 14:38:40

US3392133

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:46:11
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:13:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:18:49
User entered empty; reason for change Data Entry Error	Brandon Illickal (b) (4)	29 Sep 2020 18:15:51
User entered 'Oral (Oral)'	Brandon Illickal (b) (4)	01 Sep 2020 14:38:40

US3392133

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:46:11
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:13:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:18:49
User entered empty.	Brandon Illickal (b) (4)	01 Sep 2020 14:38:40

US3392133

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:46:11
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:13:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:18:49
User entered missing code ND - Not Done; reason for change Data Entry Error	Brandon Illickal (b) (4)	29 Sep 2020 18:15:51
User entered '90'	Brandon Illickal (b) (4)	01 Sep 2020 14:38:40

US3392133

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:46:11
User entered 'bpm'	System	01 Sep 2020 14:38:40

US3392133

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:26

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:46:11
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:13:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:18:49
User entered missing code ND - Not Done; reason for change Data Entry Error	Brandon Illickal (b) (4)	29 Sep 2020 18:15:51
User entered '16'	Brandon Illickal (b) (4)	01 Sep 2020 14:38:40

US3392133

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:46:11
User entered 'breaths/min'	System	01 Sep 2020 14:38:40

US3392133

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:26

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:46:11
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:13:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:18:49
User entered missing code ND - Not Done; reason for change Data Entry Error	Brandon Illickal (b) (4)	29 Sep 2020 18:15:51
User entered '149'	Brandon Illickal (b) (4)	01 Sep 2020 14:38:40

US3392133

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:46:11
User entered 'mmHg'	System	01 Sep 2020 14:38:40

US3392133

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:26

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:46:11
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:13:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:18:49
User entered missing code ND - Not Done; reason for change Data Entry Error	Brandon Illickal (b) (4)	29 Sep 2020 18:15:51
User entered '92'	Brandon Illickal (b) (4)	01 Sep 2020 14:38:40

US3392133

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:46:11
User entered 'mmHg'	System	01 Sep 2020 14:38:40

US3392133

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:26

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:46:11

US3392133

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:26

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:46:11

US3392133

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:26:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:46:11
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:13:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:18:59
User entered 'Yes (Y)'	Brandon Illickal (b) (4)	01 Sep 2020 14:38:47

US3392133

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:26:26

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:46:11
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:13:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:18:59
User entered '1 Sep 2020'	Brandon Illickal (b) (4)	01 Sep 2020 14:38:47

US3392133

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:26:26

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:46:11
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:13:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:19:05
User entered 'No (N)'	Brandon Illickal (b) (4)	01 Sep 2020 14:39:40

US3392133

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:26:26

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:46:11
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:13:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:19:05
User entered 'No (N)'	Brandon Illickal (b) (4)	01 Sep 2020 14:39:40

US3392133

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:26:26

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:46:11
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:13:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:19:05
User entered 'No (N)'	Brandon Illickal (b) (4)	01 Sep 2020 14:39:40

US3392133

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:26:26

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:46:11
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:13:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:19:05
User entered 'No (N)'	Brandon Illickal (b) (4)	01 Sep 2020 14:39:40

US3392133

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:26:26

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:46:11
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:13:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:19:05
User entered 'No (N)'	Brandon Illickal (b) (4)	01 Sep 2020 14:39:40

US3392133

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:26:26

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:46:11
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:13:28
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 15:19:05
User entered 'No (N)'	Brandon Illickal (b) (4)	01 Sep 2020 14:39:40

US3392133

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:26:26

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:46:11
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:13:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:19:05
User entered 'No (N)'	Brandon Illickal (b) (4)	01 Sep 2020 14:39:40

US3392133

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:26:26

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:46:11
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:13:28
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 15:19:05
User entered 'No (N)'	Brandon Illickal (b) (4)	01 Sep 2020 14:39:40

US3392133

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:26:26

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:46:11
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:13:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:19:05
User entered 'No (N)'	Brandon Illickal (b) (4)	01 Sep 2020 14:39:40

US3392133

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:26:26

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:46:11
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:13:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:19:05
User entered 'No (N)'	Brandon Illickal (b) (4)	01 Sep 2020 14:39:40

US3392133

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:26:26

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:46:11
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:13:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:19:05
User entered 'No (N)'	Brandon Illickal (b) (4)	01 Sep 2020 14:39:40

US3392133

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:26:26

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:46:11
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:13:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:19:05
User entered 'Yes (Y)'	Brandon Illickal (b) (4)	01 Sep 2020 14:39:40

US3392133

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:26:26

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:46:11
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:13:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:19:05
User entered 'Online marketing/works in office a few hours/day'	Brandon Illickal (b) (4)	01 Sep 2020 14:39:40

US3392133

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:26:26

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:46:11
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:13:28
User entered '0'	(b) (4)	01 Sep 2020 14:39:40

US3392133

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:26:26

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:46:11
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:13:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:19:05
User entered '0'	Brandon Illickal (b) (4)	01 Sep 2020 14:39:40

US3392133

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:26:26

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:46:11
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:13:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:19:05
User entered '0'	Brandon Illickal (b) (4)	01 Sep 2020 14:39:40

US3392133

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:26:26

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:46:11
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:13:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:19:05
User entered '0'	Brandon Illickal (b) (4)	01 Sep 2020 14:39:40

US3392133

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:26:26

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:46:11
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:13:28
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 15:19:05
User entered '0'	Brandon Illickal (b) (4)	01 Sep 2020 14:39:40

US3392133

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:26:26

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:46:11
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:13:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:19:05
User entered 'I'	Brandon Illickal (b) (4)	01 Sep 2020 14:39:40

US3392133

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:26:26

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:46:11
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:13:28
User entered '0'	(b) (4)	01 Sep 2020 14:39:40

US3392133

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:26:26

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:46:11
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 03:13:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:19:05
User entered empty.	Brandon Illickal (b) (4)	01 Sep 2020 14:39:40

US3392133

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:26:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:52:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:19:24
User entered 'Yes (Y)'	Brandon Illickal (b) (4)	01 Sep 2020 14:40:13

US3392133

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:26:26

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:52:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:19:24
User entered '1 Sep 2020'	Brandon Illickal (b) (4)	01 Sep 2020 14:40:13

US3392133

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:26:26

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:52:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:19:24
User entered 'Clinic (Clinic)'	Brandon Illickal (b) (4)	01 Sep 2020 14:40:13

US3392133

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:26:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User entered 'VISIT1'	System	01 Sep 2020 14:40:13

US3392133

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:26:26

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:52:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:19:30
User entered '01 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 14:24:38

US3392133

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:26:26

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:52:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:19:30
User entered '110573'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 14:24:38

US3392133

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:26:26

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:52:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:19:30
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 14:24:38

US3392133

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:26:26

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:52:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:19:30
User entered 'No (N)'	Brandon Illickal (b) (4)	01 Sep 2020 14:40:21

US3392133

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:26:26

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:52:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:19:30
User entered 'No (N)'	Brandon Illickal (b) (4)	01 Sep 2020 14:40:21

US3392133

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:26:26

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:52:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:19:30
User entered 'No (N)'	Brandon Illickal (b) (4)	01 Sep 2020 14:40:21

US3392133

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:26:26

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:52:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:19:30
User entered 'No (N)'	Brandon Illickal (b) (4)	01 Sep 2020 14:40:21

US3392133

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:26:26

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:52:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:19:30
User entered 'No (N)'	Brandon Illickal (b) (4)	01 Sep 2020 14:40:21

US3392133

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:26:26

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:52:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:19:30
User entered 'No (N)'	Brandon Illickal (b) (4)	28 Sep 2020 15:02:33
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 08:53:39
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:53:38

US3392133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:26:26

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:52:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:20:09
User closed query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 17:50:09
Query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly. ' answered with 'updated' (Site from DM).	Brandon Illickal (b) (4)	29 Sep 2020 16:15:43
User entered missing code ND - Not Done; reason for change Data Entry Error	Brandon Illickal (b) (4)	29 Sep 2020 16:15:39
User opened query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 18:37:47
User entered '73.0' in	Brandon Illickal (b) (4)	01 Sep 2020 17:35:35

US3392133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:26:26

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:52:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:20:09
User entered missing code ND - Not Done; reason for change Data Entry Error	Brandon Illickal (b) (4)	29 Sep 2020 16:15:39
User entered '200.0' lb	Brandon Illickal (b) (4)	01 Sep 2020 17:35:35

US3392133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:26:26

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:52:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:20:09
User closed query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 17:50:09
Query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly. ' answered with 'updated' (Site from DM).	Brandon Illickal (b) (4)	29 Sep 2020 16:15:43
User entered missing code ND - Not Done; reason for change Data Entry Error	Brandon Illickal (b) (4)	29 Sep 2020 16:15:39
User opened query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 18:37:47
User entered '73.0' in	Brandon Illickal (b) (4)	01 Sep 2020 17:35:35

US3392133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:26:26

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:52:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:20:09
User entered missing code ND - Not Done; reason for change Data Entry Error	Brandon Illickal (b) (4)	29 Sep 2020 16:15:39
User entered '200.0' lb	Brandon Illickal (b) (4)	01 Sep 2020 17:35:35

US3392133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:26

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User accepted default value 'Pre-Dose (PREDOSE)'	Brandon Illickal (b) (4)	01 Sep 2020 17:35:35

US3392133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:52:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:20:09
User entered 'Yes (Y)'	Brandon Illickal (b) (4)	01 Sep 2020 17:35:35

US3392133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:52:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:20:09
User entered '1 Sep 2020'	Brandon Illickal (b) (4)	01 Sep 2020 17:35:35

US3392133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:26

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:52:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:20:09
User entered '08:54'	Brandon Illickal (b) (4)	01 Sep 2020 17:35:35

US3392133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:26

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User entered '1 Sep 2020 08:54'	System	01 Sep 2020 17:35:35

US3392133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:52:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:20:09
User entered '98.5' F	Brandon Illickal (b) (4)	01 Sep 2020 17:35:35

US3392133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:52:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:20:09
User entered 'Oral (Oral)'	Brandon Illickal (b) (4)	01 Sep 2020 17:35:35

US3392133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:52:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:20:09
User entered empty.	Brandon Illickal (b) (4)	01 Sep 2020 17:35:35

US3392133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:52:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:20:09
User entered '90'	Brandon Illickal (b) (4)	01 Sep 2020 17:35:35

US3392133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User entered 'bpm'	System	01 Sep 2020 17:35:35

US3392133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:26

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:52:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:20:09
User entered '16'	Brandon Illickal (b) (4)	01 Sep 2020 17:35:35

US3392133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User entered 'breaths/min'	System	01 Sep 2020 17:35:35

US3392133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:26

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:52:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:20:09
User entered '149'	Brandon Illickal (b) (4)	01 Sep 2020 17:35:35

US3392133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User entered 'mmHg'	System	01 Sep 2020 17:35:35

US3392133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:26

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:52:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:20:09
User entered '92'	Brandon Illickal (b) (4)	01 Sep 2020 17:35:35

US3392133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User entered 'mmHg'	System	01 Sep 2020 17:35:35

US3392133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:26:26

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:52:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:20:09
User closed query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 17:50:09
Query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly. ' answered with 'updated' (Site from DM).	Brandon Illickal (b) (4)	29 Sep 2020 16:15:43
User entered missing code ND - Not Done; reason for change Data Entry Error	Brandon Illickal (b) (4)	29 Sep 2020 16:15:39
User opened query 'Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 18:37:47
User entered '73.0' in	Brandon Illickal (b) (4)	01 Sep 2020 17:35:35

US3392133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:26:26

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:52:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:20:09
User entered missing code ND - Not Done; reason for change Data Entry Error	Brandon Illickal (b) (4)	29 Sep 2020 16:15:39
User entered '200.0' lb	Brandon Illickal (b) (4)	01 Sep 2020 17:35:35

US3392133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:26

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User accepted default value 'Post-Dose (POSTDOSE)'	Brandon Illickal (b) (4)	01 Sep 2020 17:35:35

US3392133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:52:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:20:09
User entered 'Yes (Y)'	Brandon Illickal (b) (4)	01 Sep 2020 17:35:35

US3392133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:52:33
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 15:20:09
User entered '1 Sep 2020'	Brandon Illickal (b) (4)	01 Sep 2020 17:35:35

US3392133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:26

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:52:33
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 15:20:09
Query 'Per CDM: Post-dose vital signs evaluation time is less than 60 minutes after IP injection. Please reconcile and update as needed. ' canceled (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 21:57:03
User opened query 'Per CDM: Post-dose vital signs evaluation time is less than 60 minutes after IP injection. Please reconcile and update as needed. ' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 22:09:41
User entered '10:53'	Brandon Illickal (b) (4)	01 Sep 2020 17:35:35

US3392133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:26

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User entered '1 Sep 2020 10:53'	System	01 Sep 2020 17:35:35

US3392133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:52:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:20:09
User entered '98.3' F	Brandon Illickal (b) (4)	01 Sep 2020 17:35:35

US3392133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:52:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:20:09
User entered 'Oral (Oral)'	Brandon Illickal (b) (4)	01 Sep 2020 17:35:35

US3392133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:52:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:20:09
User entered empty.	Brandon Illickal (b) (4)	01 Sep 2020 17:35:35

US3392133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:52:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:20:09
User entered '82'	Brandon Illickal (b) (4)	01 Sep 2020 17:35:35

US3392133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User entered 'bpm'	System	01 Sep 2020 17:35:35

US3392133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:26

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:52:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:20:09
User entered '16'	Brandon Illickal (b) (4)	01 Sep 2020 17:35:35

US3392133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User entered 'breaths/min'	System	01 Sep 2020 17:35:35

US3392133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:52:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:20:09
User entered '152'	Brandon Illickal (b) (4)	01 Sep 2020 17:35:35

US3392133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User entered 'mmHg'	System	01 Sep 2020 17:35:35

US3392133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:26

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:52:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:20:09
User entered '97'	Brandon Illickal (b) (4)	01 Sep 2020 17:35:35

US3392133

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User entered 'mmHg'	System	01 Sep 2020 17:35:35

US3392133

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:26:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:52:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:20:16
User entered 'Yes (Y)'	Brandon Illickal (b) (4)	01 Sep 2020 14:40:28

US3392133

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:26:26

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:52:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:20:16
User entered '1 Sep 2020'	Brandon Illickal (b) (4)	01 Sep 2020 14:40:28

US3392133

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:26:26

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:52:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:21:05
User entered 'Yes (Y)'	Brandon Illickal (b) (4)	01 Sep 2020 15:39:00

US3392133

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:26:26

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:52:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:21:05
User entered empty.	Brandon Illickal (b) (4)	01 Sep 2020 15:39:00

US3392133

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:26:26

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:52:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:21:05
User entered empty.	Brandon Illickal (b) (4)	01 Sep 2020 15:39:00

US3392133

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:26:26

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User entered 'MRNA-1273 OR PLACEBO'	System	01 Sep 2020 15:39:00

US3392133

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:26:26

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:52:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:21:05
User entered '1 Sep 2020'	Brandon Illickal (b) (4)	01 Sep 2020 15:39:00

US3392133

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:26:26

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:52:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:21:05
User entered '10:21'	Brandon Illickal (b) (4)	01 Sep 2020 15:39:00

US3392133

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:26:26

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User entered '1 Sep 2020 10:21'	System	01 Sep 2020 15:39:00

US3392133

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:26:26

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:52:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:21:05
User entered 'Right Arm (RIGHT ARM)'	Brandon Illickal (b) (4)	01 Sep 2020 15:39:00

US3392133

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:26:26

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 15:21:05
User entered 'ONCE'	System	01 Sep 2020 15:39:00

US3392133

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:26:26

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User entered 'INTRAMUSCULAR'	System	01 Sep 2020 15:39:00

US3392133

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:26:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:52:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:21:44
User entered 'Yes (Y)'	Brandon Illickal (b) (4)	01 Sep 2020 14:40:53

US3392133

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:26:26

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:52:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:21:44
User entered '1 Sep 2020'	Brandon Illickal (b) (4)	01 Sep 2020 14:40:53

US3392133

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:26:26

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:52:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:21:44
User entered '09:17'	Brandon Illickal (b) (4)	01 Sep 2020 14:40:53

US3392133

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:26:26

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User entered '1 Sep 2020 09:17'	System	01 Sep 2020 14:40:53

US3392133

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:26:26

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:52:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:22:24
User entered '1 Sep 2020'	Brandon Illickal (b) (4)	01 Sep 2020 14:41:06

US3392133

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:26:26

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Brandon Illickal (b) (4)	01 Sep 2020 14:41:06

US3392133

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:26:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:52:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:22:24
User entered 'Yes (Y)'	Brandon Illickal (b) (4)	01 Sep 2020 14:41:06

US3392133

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:26:26

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:52:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:22:24
User entered '09:12'	Brandon Illickal (b) (4)	01 Sep 2020 14:41:06

US3392133

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:26:26

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User entered '1 Sep 2020 09:12'	System	01 Sep 2020 14:41:06

US3392133

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:26:26

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Brandon Illickal (b) (4)	01 Sep 2020 14:41:06

US3392133

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:26:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:52:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:22:24
User entered 'No (N)'	Brandon Illickal (b) (4)	01 Sep 2020 14:41:06

US3392133

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:26:26

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:52:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:22:24
User entered empty.	Brandon Illickal (b) (4)	01 Sep 2020 14:41:06

US3392133

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:26:26

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User entered empty.	System	01 Sep 2020 14:41:06

US3392133

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:26:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:52:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:22:31
User entered 'Yes (Y)'	Brandon Illickal (b) (4)	01 Sep 2020 14:41:10

US3392133

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:26:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User entered 'I'	System	01 Sep 2020 14:41:10

US3392133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
Data entry locked.	System	01 Sep 2020 15:39:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 15:39:00

US3392133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:26:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-01T10:53:59', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'a272f82a-feb1-4aa5-a610-cf52858a1423'	System	01 Sep 2020 15:55:40
User entered 'Yes (Y)'	System	01 Sep 2020 15:55:40

US3392133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:26:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-01T10:54:06', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'a272f82a-feb1-4aa5-a610-cf52858a1423'	System	01 Sep 2020 15:55:40
User entered '98.3'	System	01 Sep 2020 15:55:40

US3392133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:26:26

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-01T10:54:12', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'a272f82a-feb1-4aa5-a610-cf52858a1423'	System	01 Sep 2020 15:55:40
User entered 'No (N)'	System	01 Sep 2020 15:55:40

US3392133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:26:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-01T10:54:16', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'a272f82a-feb1-4aa5-a610-cf52858a1423'	System	01 Sep 2020 15:55:40
User entered '01 Sep 2020 10:54'	System	01 Sep 2020 15:55:40

US3392133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:26:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '01 Sep 2020 10:41'	System	01 Sep 2020 15:39:00

US3392133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:26:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '01 Sep 2020 13:11'	System	01 Sep 2020 15:39:00

US3392133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
Data entry locked.	System	01 Sep 2020 15:39:00
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 15:39:00

US3392133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:26:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-01T22:09:52', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '2207637a-ee76-4ccf-b975-e9f525de99aa'	System	02 Sep 2020 03:10:11
User entered 'Yes (Y)'	System	02 Sep 2020 03:10:11

US3392133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:26:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-01T22:09:57', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '2207637a-ee76-4ccf-b975-e9f525de99aa'	System	02 Sep 2020 03:10:11
User entered '98.0'	System	02 Sep 2020 03:10:11

US3392133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:26:26

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-01T22:10:01', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '2207637a-ee76-4ccf-b975-e9f525de99aa'	System	02 Sep 2020 03:10:11
User entered 'No (N)'	System	02 Sep 2020 03:10:11

US3392133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:26:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-01T22:10:06', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '2207637a-ee76-4ccf-b975-e9f525de99aa'	System	02 Sep 2020 03:10:11
User entered '01 Sep 2020 22:10'	System	02 Sep 2020 03:10:11

US3392133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:26:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '01 Sep 2020 14:06'	System	01 Sep 2020 15:39:00

US3392133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:26:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 15:39:00

US3392133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
Data entry locked.	System	01 Sep 2020 15:39:00
User entered 'Day 2'	System	01 Sep 2020 15:39:00

US3392133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:26:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-02T18:35:09', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '448e37b8-838f-463d-86ee-c8c7de784d63'	System	02 Sep 2020 23:35:27
User entered 'Yes (Y)'	System	02 Sep 2020 23:35:27

US3392133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:26:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-02T18:35:15', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '448e37b8-838f-463d-86ee-c8c7de784d63'	System	02 Sep 2020 23:35:27
User entered '98.6'	System	02 Sep 2020 23:35:27

US3392133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:26:26

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-02T18:35:18', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '448e37b8-838f-463d-86ee-c8c7de784d63'	System	02 Sep 2020 23:35:27
User entered 'No (N)'	System	02 Sep 2020 23:35:27

US3392133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:26:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-02T18:35:23', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '448e37b8-838f-463d-86ee-c8c7de784d63'	System	02 Sep 2020 23:35:27
User entered '02 Sep 2020 18:35'	System	02 Sep 2020 23:35:27

US3392133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:26:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 15:39:00

US3392133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:26:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 15:39:00

US3392133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
Data entry locked.	System	01 Sep 2020 15:39:00
User entered 'Day 3'	System	01 Sep 2020 15:39:00

US3392133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:26:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-03T12:18:15', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '27ddf523-b6c2-4b23-a1d7-22b9dff8e9fc'	System	03 Sep 2020 17:18:41
User entered 'Yes (Y)'	System	03 Sep 2020 17:18:41

US3392133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:26:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-03T12:18:24', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '27ddf523-b6c2-4b23-a1d7-22b9dff8e9fc'	System	03 Sep 2020 17:18:41
User entered '98.4'	System	03 Sep 2020 17:18:41

US3392133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:26:26

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-03T12:18:34', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '27ddf523-b6c2-4b23-a1d7-22b9dff8e9fc'	System	03 Sep 2020 17:18:41
User entered 'No (N)'	System	03 Sep 2020 17:18:41

US3392133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:26:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-03T12:18:38', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '27ddf523-b6c2-4b23-a1d7-22b9dff8e9fc'	System	03 Sep 2020 17:18:41
User entered '03 Sep 2020 12:18'	System	03 Sep 2020 17:18:41

US3392133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:26:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 15:39:00

US3392133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:26:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 15:39:00

US3392133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
Data entry locked.	System	01 Sep 2020 15:39:00
User entered 'Day 4'	System	01 Sep 2020 15:39:00

US3392133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:26:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-04T12:00:57', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'e1ddd0a0-ebe2-4270-a5d3-570535e500f9'	System	04 Sep 2020 17:01:48
User entered 'Yes (Y)'	System	04 Sep 2020 17:01:48

US3392133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:26:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-04T12:01:02', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'e1ddd0a0-ebe2-4270-a5d3-570535e500f9'	System	04 Sep 2020 17:01:48
User entered '98.4'	System	04 Sep 2020 17:01:48

US3392133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:26:26

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-04T12:01:06', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'e1ddd0a0-ebe2-4270-a5d3-570535e500f9'	System	04 Sep 2020 17:01:48
User entered 'No (N)'	System	04 Sep 2020 17:01:48

US3392133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:26:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-04T12:01:08', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'e1ddd0a0-ebe2-4270-a5d3-570535e500f9'	System	04 Sep 2020 17:01:48
User entered '04 Sep 2020 12:01'	System	04 Sep 2020 17:01:48

US3392133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:26:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 15:39:00

US3392133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:26:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 15:39:00

US3392133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
Data entry locked.	System	01 Sep 2020 15:39:00
User entered 'Day 5'	System	01 Sep 2020 15:39:00

US3392133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:26:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-05T12:40:30', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'a6de5fca-8c57-4c95-bd0f-4b96f2aaf066'	System	05 Sep 2020 17:40:44
User entered 'Yes (Y)'	System	05 Sep 2020 17:40:44

US3392133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:26:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-05T12:40:35', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'a6de5fca-8c57-4c95-bd0f-4b96f2aaf066'	System	05 Sep 2020 17:40:44
User entered '98.6'	System	05 Sep 2020 17:40:44

US3392133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:26:26

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-05T12:40:37', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'a6de5fca-8c57-4c95-bd0f-4b96f2aaf066'	System	05 Sep 2020 17:40:44
User entered 'No (N)'	System	05 Sep 2020 17:40:44

US3392133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:26:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-05T12:40:40', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'a6de5fca-8c57-4c95-bd0f-4b96f2aaf066'	System	05 Sep 2020 17:40:44
User entered '05 Sep 2020 12:40'	System	05 Sep 2020 17:40:44

US3392133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:26:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 15:39:00

US3392133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:26:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 15:39:00

US3392133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
Data entry locked.	System	01 Sep 2020 15:39:00
User entered 'Day 6'	System	01 Sep 2020 15:39:00

US3392133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:26:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-06T19:50:48', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '5210a0b4-a23b-41b0-9a0d-d29158726baf'	System	07 Sep 2020 00:51:05
User entered 'Yes (Y)'	System	07 Sep 2020 00:51:05

US3392133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:26:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-06T19:50:54', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '5210a0b4-a23b-41b0-9a0d-d29158726baf' User entered '98.2'	System	07 Sep 2020 00:51:05
	System	07 Sep 2020 00:51:05

US3392133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:26:26

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-06T19:50:59', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '5210a0b4-a23b-41b0-9a0d-d29158726baf'	System	07 Sep 2020 00:51:05
User entered 'No (N)'	System	07 Sep 2020 00:51:05

US3392133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:26:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-06T19:51:03', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '5210a0b4-a23b-41b0-9a0d-d29158726baf'	System	07 Sep 2020 00:51:05
User entered '06 Sep 2020 19:51'	System	07 Sep 2020 00:51:05

US3392133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:26:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 15:39:00

US3392133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:26:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 15:39:00

US3392133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
Data entry locked.	System	01 Sep 2020 15:39:00
User entered 'Day 7'	System	01 Sep 2020 15:39:00

US3392133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:26:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-07T13:00:25', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '3cbc8da2-d04a-4810-872f-1f7337f4c736'	System	07 Sep 2020 18:00:36
User entered 'No (N)'	System	07 Sep 2020 18:00:36

US3392133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:26:26

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-07T13:00:28', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '3cbc8da2-d04a-4810-872f-1f7337f4c736'	System	07 Sep 2020 18:00:36
User entered 'No (N)'	System	07 Sep 2020 18:00:36

US3392133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:26:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-07T13:00:32', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '3cbc8da2-d04a-4810-872f-1f7337f4c736'	System	07 Sep 2020 18:00:36
User entered '07 Sep 2020 13:00'	System	07 Sep 2020 18:00:36

US3392133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:26:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 15:39:00

US3392133

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:26:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 15:39:00

US3392133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
Data entry locked.	System	01 Sep 2020 15:39:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 15:39:00

US3392133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:26:26

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-01T10:54:24', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '03585b9c-5aa3-4aa3-b96b-c06a45782fe8'	System	01 Sep 2020 15:55:51
User entered 'None (1)'	System	01 Sep 2020 15:55:51

US3392133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:26:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-01T10:54:27', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '03585b9c-5aa3-4aa3-b96b-c06a45782fe8'	System	01 Sep 2020 15:55:51
User entered 'No (N)'	System	01 Sep 2020 15:55:51

US3392133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:26:26

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-01T10:54:30', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '03585b9c-5aa3-4aa3-b96b-c06a45782fe8'	System	01 Sep 2020 15:55:51
User entered 'No (N)'	System	01 Sep 2020 15:55:51

US3392133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:26:26

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-01T10:54:34', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '03585b9c-5aa3-4aa3-b96b-c06a45782fe8'	System	01 Sep 2020 15:55:51
User entered 'None (1)'	System	01 Sep 2020 15:55:51

US3392133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:26:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-01T10:54:38', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '03585b9c-5aa3-4aa3-b96b-c06a45782fe8'	System	01 Sep 2020 15:55:51
User entered '01 Sep 2020 10:54'	System	01 Sep 2020 15:55:51

US3392133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:26:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '01 Sep 2020 10:41'	System	01 Sep 2020 15:39:00

US3392133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:26:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '01 Sep 2020 13:11'	System	01 Sep 2020 15:39:00

US3392133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
Data entry locked.	System	01 Sep 2020 15:39:00
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 15:39:00

US3392133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:26:26

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-01T22:10:18', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'f687a77a-ebfe-4baf-a811-1d47df601c4a'	System	02 Sep 2020 03:10:36
User entered 'Does not interfere with activity (2)'	System	02 Sep 2020 03:10:36

US3392133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:26:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-01T22:10:21', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'f687a77a-ebfe-4baf-a811-1d47df601c4a'	System	02 Sep 2020 03:10:36
User entered 'No (N)'	System	02 Sep 2020 03:10:36

US3392133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:26:26

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-01T22:10:24', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'f687a77a-ebfe-4baf-a811-1d47df601c4a'	System	02 Sep 2020 03:10:36
User entered 'No (N)'	System	02 Sep 2020 03:10:36

US3392133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:26:26

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-01T22:10:28', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'f687a77a-ebfe-4baf-a811-1d47df601c4a'	System	02 Sep 2020 03:10:36
User entered 'None (1)'	System	02 Sep 2020 03:10:36

US3392133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:26:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-01T22:10:31', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'f687a77a-ebfe-4baf-a811-1d47df601c4a'	System	02 Sep 2020 03:10:36
User entered '01 Sep 2020 22:10'	System	02 Sep 2020 03:10:36

US3392133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:26:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '01 Sep 2020 14:06'	System	01 Sep 2020 15:39:00

US3392133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:26:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 15:39:00

US3392133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
Data entry locked.	System	01 Sep 2020 15:39:00
User entered 'Day 2'	System	01 Sep 2020 15:39:00

US3392133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:26:26

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-02T18:35:27', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '9807a970-3c97-4199-ae64-df24d97e6643'	System	02 Sep 2020 23:35:44
User entered 'None (1)'	System	02 Sep 2020 23:35:44

US3392133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:26:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-02T18:35:30', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '9807a970-3c97-4199-ae64-df24d97e6643'	System	02 Sep 2020 23:35:44
User entered 'No (N)'	System	02 Sep 2020 23:35:44

US3392133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:26:26

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-02T18:35:32', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '9807a970-3c97-4199-ae64-df24d97e6643'	System	02 Sep 2020 23:35:44
User entered 'No (N)'	System	02 Sep 2020 23:35:44

US3392133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:26:26

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-02T18:35:35', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '9807a970-3c97-4199-ae64-df24d97e6643'	System	02 Sep 2020 23:35:44
User entered 'None (1)'	System	02 Sep 2020 23:35:44

US3392133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:26:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-02T18:35:39', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '9807a970-3c97-4199-ae64-df24d97e6643'	System	02 Sep 2020 23:35:44
User entered '02 Sep 2020 18:35'	System	02 Sep 2020 23:35:44

US3392133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:26:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 15:39:00

US3392133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:26:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 15:39:00

US3392133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
Data entry locked.	System	01 Sep 2020 15:39:00
User entered 'Day 3'	System	01 Sep 2020 15:39:00

US3392133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:26:26

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-03T12:18:43', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'ffd68b5f-54a2-4601-a0f0-cb5d64685151'	System	03 Sep 2020 17:19:10
User entered 'None (1)'	System	03 Sep 2020 17:19:10

US3392133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:26:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-03T12:18:51', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'ffd68b5f-54a2-4601-a0f0-cb5d64685151'	System	03 Sep 2020 17:19:10
User entered 'No (N)'	System	03 Sep 2020 17:19:10

US3392133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:26:26

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-03T12:18:56', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'ffd68b5f-54a2-4601-a0f0-cb5d64685151'	System	03 Sep 2020 17:19:10
User entered 'No (N)'	System	03 Sep 2020 17:19:10

US3392133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:26:26

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-03T12:19:04', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'ffd68b5f-54a2-4601-a0f0-cb5d64685151'	System	03 Sep 2020 17:19:10
User entered 'None (1)'	System	03 Sep 2020 17:19:10

US3392133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:26:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-03T12:19:07', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'ffd68b5f-54a2-4601-a0f0-cb5d64685151'	System	03 Sep 2020 17:19:10
User entered '03 Sep 2020 12:19'	System	03 Sep 2020 17:19:10

US3392133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:26:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 15:39:00

US3392133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:26:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 15:39:00

US3392133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
Data entry locked.	System	01 Sep 2020 15:39:00
User entered 'Day 4'	System	01 Sep 2020 15:39:00

US3392133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:26:26

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-04T12:01:12', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '3326bc51-f233-4ed1-be06-dfd0b5396740'	System	04 Sep 2020 17:02:07
User entered 'None (1)'	System	04 Sep 2020 17:02:07

US3392133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:26:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-04T12:01:14', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '3326bc51-f233-4ed1-be06-dfd0b5396740'	System	04 Sep 2020 17:02:07
User entered 'No (N)'	System	04 Sep 2020 17:02:07

US3392133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:26:26

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-04T12:01:16', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '3326bc51-f233-4ed1-be06-dfd0b5396740'	System	04 Sep 2020 17:02:07
User entered 'No (N)'	System	04 Sep 2020 17:02:07

US3392133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:26:26

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-04T12:01:19', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '3326bc51-f233-4ed1-be06-dfd0b5396740'	System	04 Sep 2020 17:02:07
User entered 'None (1)'	System	04 Sep 2020 17:02:07

US3392133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:26:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-04T12:01:21', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '3326bc51-f233-4ed1-be06-dfd0b5396740' User entered '04 Sep 2020 12:01'	System	04 Sep 2020 17:02:07
	System	04 Sep 2020 17:02:07

US3392133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:26:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 15:39:00

US3392133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:26:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 15:39:00

US3392133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
Data entry locked.	System	01 Sep 2020 15:39:00
User entered 'Day 5'	System	01 Sep 2020 15:39:00

US3392133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:26:26

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-05T12:40:44', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '0968357e-f6a0-419a-9391-d7da7f11de80'	System	05 Sep 2020 17:40:58
User entered 'None (1)'	System	05 Sep 2020 17:40:58

US3392133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:26:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-05T12:40:46', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '0968357e-f6a0-419a-9391-d7da7f11de80'	System	05 Sep 2020 17:40:58
User entered 'No (N)'	System	05 Sep 2020 17:40:58

US3392133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:26:26

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-05T12:40:48', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '0968357e-f6a0-419a-9391-d7da7f11de80'	System	05 Sep 2020 17:40:58
User entered 'No (N)'	System	05 Sep 2020 17:40:58

US3392133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:26:26

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-05T12:40:51', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '0968357e-f6a0-419a-9391-d7da7f11de80'	System	05 Sep 2020 17:40:58
User entered 'None (1)'	System	05 Sep 2020 17:40:58

US3392133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:26:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-05T12:40:54', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '0968357e-f6a0-419a-9391-d7da7f11de80'	System	05 Sep 2020 17:40:58
User entered '05 Sep 2020 12:40'	System	05 Sep 2020 17:40:58

US3392133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:26:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 15:39:00

US3392133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:26:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 15:39:00

US3392133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
Data entry locked.	System	01 Sep 2020 15:39:00
User entered 'Day 6'	System	01 Sep 2020 15:39:00

US3392133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:26:26

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-06T19:51:08', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '30f91b8e-9b1b-42b8-87d9-28eb60e1fb3b'	System	07 Sep 2020 00:51:26
User entered 'None (1)'	System	07 Sep 2020 00:51:26

US3392133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:26:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-06T19:51:10', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '30f91b8e-9b1b-42b8-87d9-28eb60e1fb3b'	System	07 Sep 2020 00:51:26
User entered 'No (N)'	System	07 Sep 2020 00:51:26

US3392133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:26:26

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-06T19:51:13', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '30f91b8e-9b1b-42b8-87d9-28eb60e1fb3b'	System	07 Sep 2020 00:51:26
User entered 'No (N)'	System	07 Sep 2020 00:51:26

US3392133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:26:26

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-06T19:51:16', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '30f91b8e-9b1b-42b8-87d9-28eb60e1fb3b'	System	07 Sep 2020 00:51:26
User entered 'None (1)'	System	07 Sep 2020 00:51:26

US3392133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:26:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-06T19:51:24', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '30f91b8e-9b1b-42b8-87d9-28eb60e1fb3b'	System	07 Sep 2020 00:51:26
User entered '06 Sep 2020 19:51'	System	07 Sep 2020 00:51:26

US3392133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:26:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 15:39:00

US3392133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:26:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 15:39:00

US3392133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
Data entry locked.	System	01 Sep 2020 15:39:00
User entered 'Day 7'	System	01 Sep 2020 15:39:00

US3392133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:26:26

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-07T13:00:36', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'b93fda40-2553-413b-802f-36cf84c7cfc9'	System	07 Sep 2020 18:00:47
User entered 'None (1)'	System	07 Sep 2020 18:00:47

US3392133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:26:26

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-07T13:00:39', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'b93fda40-2553-413b-802f-36cf84c7cfc9'	System	07 Sep 2020 18:00:47
User entered 'No (N)'	System	07 Sep 2020 18:00:47

US3392133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:26:26

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-07T13:00:42', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'b93fda40-2553-413b-802f-36cf84c7cfc9'	System	07 Sep 2020 18:00:47
User entered 'No (N)'	System	07 Sep 2020 18:00:47

US3392133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:26:26

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-07T13:00:44', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'b93fda40-2553-413b-802f-36cf84c7cfc9'	System	07 Sep 2020 18:00:47
User entered 'None (1)'	System	07 Sep 2020 18:00:47

US3392133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:26:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-07T13:00:46', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'b93fda40-2553-413b-802f-36cf84c7cfc9'	System	07 Sep 2020 18:00:47
User entered '07 Sep 2020 13:00'	System	07 Sep 2020 18:00:47

US3392133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:26:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 15:39:00

US3392133

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:26:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 15:39:00

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
Data entry locked.	System	01 Sep 2020 15:39:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 15:39:00

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:26:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-01T10:54:47', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'da6b5f8e-c30b-4728-b2e3-44f0327d8c0d'	System	01 Sep 2020 15:55:50
User entered 'None (0)'	System	01 Sep 2020 15:55:50

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:26:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-01T10:54:49', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'da6b5f8e-c30b-4728-b2e3-44f0327d8c0d'	System	01 Sep 2020 15:55:50
User entered 'None (0)'	System	01 Sep 2020 15:55:50

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:26:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-01T10:54:52', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'da6b5f8e-c30b-4728-b2e3-44f0327d8c0d'	System	01 Sep 2020 15:55:50
User entered 'None (0)'	System	01 Sep 2020 15:55:50

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:26:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-01T10:54:55', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'da6b5f8e-c30b-4728-b2e3-44f0327d8c0d'	System	01 Sep 2020 15:55:50
User entered 'None (0)'	System	01 Sep 2020 15:55:50

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:26:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-01T10:54:56', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'da6b5f8e-c30b-4728-b2e3-44f0327d8c0d'	System	01 Sep 2020 15:55:50
User entered 'None (0)'	System	01 Sep 2020 15:55:50

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:26:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-01T10:54:58', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'da6b5f8e-c30b-4728-b2e3-44f0327d8c0d'	System	01 Sep 2020 15:55:50
User entered 'None (0)'	System	01 Sep 2020 15:55:50

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:26:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-01T10:55:04', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'da6b5f8e-c30b-4728-b2e3-44f0327d8c0d'	System	01 Sep 2020 15:55:50
User entered 'No (N)'	System	01 Sep 2020 15:55:50

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:26:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-01T10:55:08', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'da6b5f8e-c30b-4728-b2e3-44f0327d8c0d'	System	01 Sep 2020 15:55:50
User entered '01 Sep 2020 10:55'	System	01 Sep 2020 15:55:50

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:26:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '01 Sep 2020 10:41'	System	01 Sep 2020 15:39:00

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:26:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '01 Sep 2020 13:11'	System	01 Sep 2020 15:39:00

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
Data entry locked.	System	01 Sep 2020 15:39:00
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 15:39:00

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:26:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-01T22:10:36', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '8a987473-722f-43bd-b5cc-96eedb589d48'	System	02 Sep 2020 03:10:59
User entered 'None (0)'	System	02 Sep 2020 03:10:59

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:26:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-01T22:10:38', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '8a987473-722f-43bd-b5cc-96eedb589d48'	System	02 Sep 2020 03:10:59
User entered 'None (0)'	System	02 Sep 2020 03:10:59

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:26:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-01T22:10:41', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '8a987473-722f-43bd-b5cc-96eedb589d48'	System	02 Sep 2020 03:10:59
User entered 'None (0)'	System	02 Sep 2020 03:10:59

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:26:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-01T22:10:44', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '8a987473-722f-43bd-b5cc-96eedb589d48'	System	02 Sep 2020 03:10:59
User entered 'None (0)'	System	02 Sep 2020 03:10:59

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:26:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-01T22:10:47', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '8a987473-722f-43bd-b5cc-96eedb589d48'	System	02 Sep 2020 03:10:59
User entered 'None (0)'	System	02 Sep 2020 03:10:59

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:26:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-01T22:10:49', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '8a987473-722f-43bd-b5cc-96eedb589d48'	System	02 Sep 2020 03:10:59
User entered 'None (0)'	System	02 Sep 2020 03:10:59

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:26:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-01T22:10:53', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '8a987473-722f-43bd-b5cc-96eedb589d48'	System	02 Sep 2020 03:10:59
User entered 'No (N)'	System	02 Sep 2020 03:10:59

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:26:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-01T22:10:55', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '8a987473-722f-43bd-b5cc-96eedb589d48'	System	02 Sep 2020 03:10:59
User entered '01 Sep 2020 22:10'	System	02 Sep 2020 03:10:59

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:26:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '01 Sep 2020 14:06'	System	01 Sep 2020 15:39:00

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:26:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 15:39:00

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
Data entry locked.	System	01 Sep 2020 15:39:00
User entered 'Day 2'	System	01 Sep 2020 15:39:00

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:26:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-02T18:35:45', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'a313577c-bfe7-4718-aa2f-de74ed8c9920'	System	02 Sep 2020 23:36:12
User entered 'None (0)'	System	02 Sep 2020 23:36:12

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:26:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-02T18:35:47', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'a313577c-bfe7-4718-aa2f-de74ed8c9920'	System	02 Sep 2020 23:36:12
User entered 'None (0)'	System	02 Sep 2020 23:36:12

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:26:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-02T18:35:49', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'a313577c-bfe7-4718-aa2f-de74ed8c9920'	System	02 Sep 2020 23:36:12
User entered 'None (0)'	System	02 Sep 2020 23:36:12

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:26:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-02T18:35:51', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'a313577c-bfe7-4718-aa2f-de74ed8c9920'	System	02 Sep 2020 23:36:12
User entered 'None (0)'	System	02 Sep 2020 23:36:12

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:26:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-02T18:35:53', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'a313577c-bfe7-4718-aa2f-de74ed8c9920'	System	02 Sep 2020 23:36:12
User entered 'None (0)'	System	02 Sep 2020 23:36:12

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:26:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-02T18:35:55', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'a313577c-bfe7-4718-aa2f-de74ed8c9920'	System	02 Sep 2020 23:36:12
User entered 'None (0)'	System	02 Sep 2020 23:36:12

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:26:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-02T18:36:03', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'a313577c-bfe7-4718-aa2f-de74ed8c9920'	System	02 Sep 2020 23:36:12
User entered 'No (N)'	System	02 Sep 2020 23:36:12

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:26:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-02T18:36:06', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'a313577c-bfe7-4718-aa2f-de74ed8c9920'	System	02 Sep 2020 23:36:12
User entered '02 Sep 2020 18:36'	System	02 Sep 2020 23:36:12

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:26:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 15:39:00

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:26:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 15:39:00

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
Data entry locked.	System	01 Sep 2020 15:39:00
User entered 'Day 3'	System	01 Sep 2020 15:39:00

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:26:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-03T12:19:12', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'f6171207-5d8f-4d6e-9436-1de7cfe00e91'	System	03 Sep 2020 17:19:41
User entered 'None (0)'	System	03 Sep 2020 17:19:41

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:26:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-03T12:19:15', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'f6171207-5d8f-4d6e-9436-1de7cfe00e91'	System	03 Sep 2020 17:19:41
User entered 'None (0)'	System	03 Sep 2020 17:19:41

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:26:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-03T12:19:18', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'f6171207-5d8f-4d6e-9436-1de7cfe00e91'	System	03 Sep 2020 17:19:41
User entered 'None (0)'	System	03 Sep 2020 17:19:41

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:26:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-03T12:19:21', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'f6171207-5d8f-4d6e-9436-1de7cfe00e91'	System	03 Sep 2020 17:19:41
User entered 'None (0)'	System	03 Sep 2020 17:19:41

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:26:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-03T12:19:24', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'f6171207-5d8f-4d6e-9436-1de7cfe00e91'	System	03 Sep 2020 17:19:41
User entered 'None (0)'	System	03 Sep 2020 17:19:41

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:26:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-03T12:19:27', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'f6171207-5d8f-4d6e-9436-1de7cfe00e91'	System	03 Sep 2020 17:19:41
User entered 'None (0)'	System	03 Sep 2020 17:19:41

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:26:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-03T12:19:31', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'f6171207-5d8f-4d6e-9436-1de7cfe00e91'	System	03 Sep 2020 17:19:41
User entered 'No (N)'	System	03 Sep 2020 17:19:41

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:26:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-03T12:19:34', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'f6171207-5d8f-4d6e-9436-1de7cfe00e91'	System	03 Sep 2020 17:19:41
User entered '03 Sep 2020 12:19'	System	03 Sep 2020 17:19:41

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:26:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 15:39:00

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:26:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 15:39:00

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
Data entry locked.	System	01 Sep 2020 15:39:00
User entered 'Day 4'	System	01 Sep 2020 15:39:00

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:26:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-04T12:01:25', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'ef8abe8d-965b-4baf-a9c8-1b3e1b40cedb'	System	04 Sep 2020 17:02:29
User entered 'None (0)'	System	04 Sep 2020 17:02:29

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:26:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-04T12:01:26', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'ef8abe8d-965b-4baf-a9c8-1b3e1b40cedb'	System	04 Sep 2020 17:02:29
User entered 'None (0)'	System	04 Sep 2020 17:02:29

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:26:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-04T12:01:28', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'ef8abe8d-965b-4baf-a9c8-1b3e1b40cedb'	System	04 Sep 2020 17:02:29
User entered 'None (0)'	System	04 Sep 2020 17:02:29

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:26:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-04T12:01:30', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'ef8abe8d-965b-4baf-a9c8-1b3e1b40cedb'	System	04 Sep 2020 17:02:29
User entered 'None (0)'	System	04 Sep 2020 17:02:29

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:26:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-04T12:01:32', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'ef8abe8d-965b-4baf-a9c8-1b3e1b40cedb'	System	04 Sep 2020 17:02:29
User entered 'None (0)'	System	04 Sep 2020 17:02:29

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:26:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-04T12:01:34', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'ef8abe8d-965b-4baf-a9c8-1b3e1b40cedb'	System	04 Sep 2020 17:02:29
User entered 'None (0)'	System	04 Sep 2020 17:02:29

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:26:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-04T12:01:38', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'ef8abe8d-965b-4baf-a9c8-1b3e1b40cedb'	System	04 Sep 2020 17:02:29
User entered 'No (N)'	System	04 Sep 2020 17:02:29

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:26:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-04T12:01:40', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'ef8abe8d-965b-4baf-a9c8-1b3e1b40cedb'	System	04 Sep 2020 17:02:29
User entered '04 Sep 2020 12:01'	System	04 Sep 2020 17:02:29

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:26:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 15:39:00

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:26:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 15:39:00

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
Data entry locked.	System	01 Sep 2020 15:39:00
User entered 'Day 5'	System	01 Sep 2020 15:39:00

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:26:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-05T12:40:57', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '3fb30e13-87e4-48b2-8f3e-aab76ed5b635'	System	05 Sep 2020 17:41:17
User entered 'None (0)'	System	05 Sep 2020 17:41:17

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:26:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-05T12:40:59', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '3fb30e13-87e4-48b2-8f3e-aab76ed5b635'	System	05 Sep 2020 17:41:17
User entered 'None (0)'	System	05 Sep 2020 17:41:17

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:26:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-05T12:41:01', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '3fb30e13-87e4-48b2-8f3e-aab76ed5b635'	System	05 Sep 2020 17:41:17
User entered 'None (0)'	System	05 Sep 2020 17:41:17

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:26:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-05T12:41:03', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '3fb30e13-87e4-48b2-8f3e-aab76ed5b635'	System	05 Sep 2020 17:41:17
User entered 'None (0)'	System	05 Sep 2020 17:41:17

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:26:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-05T12:41:04', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '3fb30e13-87e4-48b2-8f3e-aab76ed5b635'	System	05 Sep 2020 17:41:17
User entered 'None (0)'	System	05 Sep 2020 17:41:17

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:26:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-05T12:41:06', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '3fb30e13-87e4-48b2-8f3e-aab76ed5b635'	System	05 Sep 2020 17:41:17
User entered 'None (0)'	System	05 Sep 2020 17:41:17

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:26:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-05T12:41:10', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '3fb30e13-87e4-48b2-8f3e-aab76ed5b635'	System	05 Sep 2020 17:41:17
User entered 'No (N)'	System	05 Sep 2020 17:41:17

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:26:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-05T12:41:12', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '3fb30e13-87e4-48b2-8f3e-aab76ed5b635'	System	05 Sep 2020 17:41:17
User entered '05 Sep 2020 12:41'	System	05 Sep 2020 17:41:17

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:26:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 15:39:00

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:26:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 15:39:00

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
Data entry locked.	System	01 Sep 2020 15:39:00
User entered 'Day 6'	System	01 Sep 2020 15:39:00

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:26:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-06T19:51:38', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'c7834d62-d465-4fbb-bde5-9a691b8af6d3'	System	07 Sep 2020 00:51:56
User entered 'None (0)'	System	07 Sep 2020 00:51:56

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:26:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-06T19:51:40', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'c7834d62-d465-4fbb-bde5-9a691b8af6d3'	System	07 Sep 2020 00:51:56
User entered 'None (0)'	System	07 Sep 2020 00:51:56

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:26:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-06T19:51:42', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'c7834d62-d465-4fbb-bde5-9a691b8af6d3'	System	07 Sep 2020 00:51:56
User entered 'None (0)'	System	07 Sep 2020 00:51:56

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:26:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-06T19:51:44', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'c7834d62-d465-4fbb-bde5-9a691b8af6d3'	System	07 Sep 2020 00:51:56
User entered 'None (0)'	System	07 Sep 2020 00:51:56

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:26:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-06T19:51:46', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'c7834d62-d465-4fbb-bde5-9a691b8af6d3'	System	07 Sep 2020 00:51:56
User entered 'None (0)'	System	07 Sep 2020 00:51:56

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:26:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-06T19:51:47', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'c7834d62-d465-4fbb-bde5-9a691b8af6d3'	System	07 Sep 2020 00:51:56
User entered 'None (0)'	System	07 Sep 2020 00:51:56

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:26:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-06T19:51:50', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'c7834d62-d465-4fbb-bde5-9a691b8af6d3'	System	07 Sep 2020 00:51:56
User entered 'No (N)'	System	07 Sep 2020 00:51:56

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:26:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-06T19:51:52', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'c7834d62-d465-4fbb-bde5-9a691b8af6d3'	System	07 Sep 2020 00:51:56
User entered '06 Sep 2020 19:51'	System	07 Sep 2020 00:51:56

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:26:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 15:39:00

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:26:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 15:39:00

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
Data entry locked.	System	01 Sep 2020 15:39:00
User entered 'Day 7'	System	01 Sep 2020 15:39:00

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:26:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-07T13:00:49', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '1cf105a4-dc87-4855-bc5a-df4bf3888f18'	System	07 Sep 2020 18:01:15
User entered 'None (0)'	System	07 Sep 2020 18:01:15

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:26:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-07T13:00:56', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '1cf105a4-dc87-4855-bc5a-df4bf3888f18'	System	07 Sep 2020 18:01:15
User entered 'None (0)'	System	07 Sep 2020 18:01:15

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:26:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-07T13:00:59', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '1cf105a4-dc87-4855-bc5a-df4bf3888f18'	System	07 Sep 2020 18:01:15
User entered 'None (0)'	System	07 Sep 2020 18:01:15

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:26:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-07T13:01:00', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '1cf105a4-dc87-4855-bc5a-df4bf3888f18'	System	07 Sep 2020 18:01:15
User entered 'None (0)'	System	07 Sep 2020 18:01:15

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:26:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-07T13:01:02', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '1cf105a4-dc87-4855-bc5a-df4bf3888f18'	System	07 Sep 2020 18:01:15
User entered 'None (0)'	System	07 Sep 2020 18:01:15

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:26:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-07T13:01:04', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '1cf105a4-dc87-4855-bc5a-df4bf3888f18'	System	07 Sep 2020 18:01:15
User entered 'None (0)'	System	07 Sep 2020 18:01:15

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:26:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-07T13:01:06', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '1cf105a4-dc87-4855-bc5a-df4bf3888f18'	System	07 Sep 2020 18:01:15
User entered 'No (N)'	System	07 Sep 2020 18:01:15

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:26:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-07T13:01:10', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '1cf105a4-dc87-4855-bc5a-df4bf3888f18'	System	07 Sep 2020 18:01:15
User entered '07 Sep 2020 13:01'	System	07 Sep 2020 18:01:15

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:26:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 15:39:00

US3392133

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:26:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 15:39:00

US3392133

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:06:03
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 15:22:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 22:32:28

US3392133

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:26

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:06:03
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 15:22:52
User entered '8 Sep 2020'	(b) (4), (b) (6)	16 Sep 2020 22:32:28

US3392133

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:06:03
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 15:22:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	16 Sep 2020 22:32:28

US3392133

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:41
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:06:03
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 15:22:52
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 22:32:28

US3392133

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:33
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:06:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:23:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 22:32:33

US3392133

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:33
User entered 'I'	System	16 Sep 2020 22:32:33

US3392133

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:33
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:32:42
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 15:23:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 22:32:50

US3392133

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:26

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:33
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:32:42
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 15:23:43
User entered '16 Sep 2020'	(b) (4), (b) (6)	16 Sep 2020 22:32:50

US3392133

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:33
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:32:42
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 15:23:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	16 Sep 2020 22:32:50

US3392133

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:33
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:32:42
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 15:23:43
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 22:32:50

US3392133

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:33
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:32:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:23:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 22:32:56

US3392133

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 18:22:33
User entered 'I'	System	16 Sep 2020 22:32:56

US3392133

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:13:46
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:13:15
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 15:24:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 13:59:05

US3392133

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:26

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:13:46
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:13:15
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 15:24:10
User entered '22 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 13:59:05

US3392133

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:13:46
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:13:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 15:24:10
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	22 Sep 2020 13:59:05

US3392133

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:13:46
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:13:15
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 15:24:10
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 13:59:05

US3392133

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:13:46
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 02:13:15
DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 15:24:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 13:59:11

US3392133

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:13:46
User entered 'I'	System	22 Sep 2020 13:59:11

US3392133

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:26:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:45
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:57:33
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	28 Sep 2020 14:56:22

US3392133

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:26:26

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:45
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:57:33
User entered '28 Sep 2020'	Brenda Lawson (b) (4)	28 Sep 2020 14:56:22

US3392133

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:26:26

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:57:33
User entered 'Clinic (Clinic)'	Brenda Lawson (b) (4) (b) (4)	28 Sep 2020 14:56:22

US3392133

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:26:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User entered 'VISIT2'	System	28 Sep 2020 14:56:22

US3392133

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:26

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User accepted default value 'Pre-Dose (PREDOSE)'	Brenda Lawson (b) (4)	28 Sep 2020 15:02:44
	(b) (4)	

US3392133

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:59:02
User entered 'Yes (Y)'	Brenda Lawson (b) (4) (b) (4)	28 Sep 2020 15:02:44

US3392133

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:59:02
User entered '28 Sep 2020'	Brenda Lawson (b) (4) (b) (4)	28 Sep 2020 15:02:44

US3392133

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:26

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:00:22
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:45
User closed query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	(b) (4)	
DataPoint Un-verified.	System	16 Nov 2020 19:02:05
	Heather Salisbury (b) (4)	16 Nov 2020 19:02:05
User entered '08:45' reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	Heather Salisbury (b) (4)	16 Nov 2020 19:02:05
	(b) (4)	
User opened query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	15 Oct 2020 15:59:02
User entered '09:57'	System	
		28 Sep 2020 15:02:44
	Brenda Lawson (b) (4)	
	(b) (4)	28 Sep 2020 15:02:44

US3392133

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:26

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User entered '28 Sep 2020 08:45'	System	16 Nov 2020 19:02:05
User entered '28 Sep 2020 09:57'	System	28 Sep 2020 15:02:44

US3392133

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:59:02
User entered '98.7' F	Brenda Lawson (b) (4) (b) (4)	28 Sep 2020 15:02:44

US3392133

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:59:02
User entered 'Oral (Oral)'	Brenda Lawson (b) (4) (b) (4)	28 Sep 2020 15:02:44

US3392133

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:59:02
User entered empty.	Brenda Lawson (b) (4) (b) (4)	28 Sep 2020 15:02:44

US3392133

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:45
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:59:02
User entered '89'	Brenda Lawson (b) (4)	28 Sep 2020 15:02:44

US3392133

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User entered 'bpm'	System	28 Sep 2020 15:02:44

US3392133

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:26

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:59:02
User entered '16'	Brenda Lawson (b) (4) (b) (4)	28 Sep 2020 15:02:44

US3392133

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User entered 'breaths/min'	System	28 Sep 2020 15:02:44

US3392133

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:26

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:59:02
User entered '147'	Brenda Lawson (b) (4) (b) (4)	28 Sep 2020 15:02:44

US3392133

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User entered 'mmHg'	System	28 Sep 2020 15:02:44

US3392133

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:59:02
User entered '82'	Brenda Lawson (b) (4) (b) (4)	28 Sep 2020 15:02:44

US3392133

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User entered 'mmHg'	System	28 Sep 2020 15:02:44

US3392133

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:26

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User accepted default value 'Post-Dose (POSTDOSE)'	Brenda Lawson (b) (4) (b) (4)	28 Sep 2020 15:02:44

US3392133

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:59:02
User entered 'Yes (Y)'	Brenda Lawson (b) (4) (b) (4)	28 Sep 2020 15:02:44

US3392133

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:59:02
User entered '28 Sep 2020'	Brenda Lawson (b) (4) (b) (4)	28 Sep 2020 15:02:44

US3392133

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:26

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:00:22
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:45
DataPoint Un-verified.	(b) (4) Heather Salisbury (b) (4)	16 Nov 2020 19:02:43
User entered '09:59' reason for change: Data Entry Error	(b) (4) Heather Salisbury (b) (4)	16 Nov 2020 19:02:43
User closed query 'Post-dose Time is prior to Pre-dose Time. Please review and reconcile.' (Site from System).	System	16 Nov 2020 19:02:05
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:59:02
User opened query 'Post-dose Time is prior to Pre-dose Time. Please review and reconcile.' (Site from System).	System	29 Sep 2020 16:27:38
User closed query 'Data is required. Please provide.' (Site from System).	System	29 Sep 2020 16:27:38
Query 'Data is required. Please provide.' answered by System data change (Site from System).		29 Sep 2020 16:27:38
User entered '09:46' reason for change: Data Entry Error	Brandon Illickal (b) (4)	29 Sep 2020 16:27:38
User opened query 'Data is required. Please provide.' (Site from System).	System	28 Sep 2020 15:02:44
User entered empty.	Brenda Lawson (b) (4) (b) (4)	28 Sep 2020 15:02:44

US3392133

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:26

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User entered '28 Sep 2020 09:59'	System	16 Nov 2020 19:02:43
User entered '28 Sep 2020 09:46'	System	29 Sep 2020 16:27:38
User entered empty.	System	28 Sep 2020 15:02:44

US3392133

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:45
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:59:02
User entered '98.3' F	Brenda Lawson (b) (4)	28 Sep 2020 15:02:44

US3392133

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:59:02
User entered 'Oral (Oral)'	Brenda Lawson (b) (4) (b) (4)	28 Sep 2020 15:02:44

US3392133

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:59:02
User entered empty.	Brenda Lawson (b) (4) (b) (4)	28 Sep 2020 15:02:44

US3392133

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:59:02
User entered '89'	Brenda Lawson (b) (4) (b) (4)	28 Sep 2020 15:02:44

US3392133

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User entered 'bpm'	System	28 Sep 2020 15:02:44

US3392133

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:26

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:59:02
User entered '14'	Brenda Lawson (b) (4) (b) (4)	28 Sep 2020 15:02:44

US3392133

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User entered 'breaths/min'	System	28 Sep 2020 15:02:44

US3392133

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:59:02
User entered '152'	Brenda Lawson (b) (4) (b) (4)	28 Sep 2020 15:02:44

US3392133

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User entered 'mmHg'	System	28 Sep 2020 15:02:44

US3392133

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:59:02
User entered '99'	Brenda Lawson (b) (4) (b) (4)	28 Sep 2020 15:02:44

US3392133

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User entered 'mmHg'	System	28 Sep 2020 15:02:44

US3392133

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:26:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:59:17
User entered 'Yes (Y)'	Brenda Lawson (b) (4) (b) (4)	28 Sep 2020 14:56:36

US3392133

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:26:26

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:45
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:59:17
User entered '28 Sep 2020'	Brenda Lawson (b) (4)	28 Sep 2020 14:56:36

US3392133

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:26:26

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:59:56
User entered 'Yes (Y)'	Brenda Lawson (b) (4) (b) (4)	28 Sep 2020 14:35:48

US3392133

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:26:26

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:59:56
User entered empty.	Brenda Lawson (b) (4) (b) (4)	28 Sep 2020 14:35:48

US3392133

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:26:26

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:45
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:59:56
User entered empty.	Brenda Lawson (b) (4)	28 Sep 2020 14:35:48

US3392133

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:26:26

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User entered 'MRNA-1273 OR PLACEBO'	System	28 Sep 2020 14:35:48

US3392133

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:26:26

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:59:56
User entered '28 Sep 2020'	Brenda Lawson (b) (4) (b) (4)	28 Sep 2020 14:35:48

US3392133

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:26:26

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 15:59:56
User entered '09:28'	Brenda Lawson (b) (4) (b) (4)	28 Sep 2020 14:35:48

US3392133

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:26:26

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User entered '28 Sep 2020 09:28'	System	28 Sep 2020 14:35:48

US3392133

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:26:26

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:00:38
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:45
User closed query 'Per CDM: Per protocol, the second dose of IP should be administered in the same arm as the first dose.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 05:35:17
Query 'Per CDM: Per protocol, the second dose of IP should be administered in the same arm as the first dose.' answered with 'updated. user error' (Site from DM).	Heather Salisbury (b) (4) (b) (4)	16 Nov 2020 19:03:44
DataPoint Un-verified.	Heather Salisbury (b) (4) (b) (4)	16 Nov 2020 19:03:17
User entered 'Right Arm (RIGHT ARM)' reason for change: Data Entry Error	Heather Salisbury (b) (4) (b) (4)	16 Nov 2020 19:03:17
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:59:56
User opened query 'Per CDM: Per protocol, the second dose of IP should be administered in the same arm as the first dose.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 17:34:38
Query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' canceled (Site from System).	(b) (4), (b) (6)	30 Sep 2020 17:32:59
User opened query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	System	28 Sep 2020 14:35:48
User entered 'Left Arm (LEFT ARM)'	Brenda Lawson (b) (4) (b) (4)	28 Sep 2020 14:35:48

US3392133

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:26:26

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 15:59:56
User entered 'ONCE'	System	28 Sep 2020 14:35:48

US3392133

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:26:26

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User entered 'INTRAMUSCULAR'	System	28 Sep 2020 14:35:48

US3392133

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:26:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:00:24
User entered 'Yes (Y)'	Brenda Lawson (b) (4) (b) (4)	28 Sep 2020 14:58:06

US3392133

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:26:26

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:00:24
User entered '28 Sep 2020'	Brenda Lawson (b) (4) (b) (4)	28 Sep 2020 14:58:06

US3392133

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:26:26

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:00:24
User entered '08:55' reason for change: Data Entry Error	Brenda Lawson (b) (4)	28 Sep 2020 14:58:26
User entered '08:52'	(b) (4) Brenda Lawson (b) (4) (b) (4)	28 Sep 2020 14:58:06

US3392133

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:26:26

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User entered '28 Sep 2020 08:55'	System	28 Sep 2020 14:58:26
User entered '28 Sep 2020 08:52'	System	28 Sep 2020 14:58:06

US3392133

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:26:26

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:00:44
User entered '28 Sep 2020'	Brenda Lawson (b) (4) (b) (4)	28 Sep 2020 14:58:42

US3392133

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:26:26

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Brenda Lawson (b) (4)	28 Sep 2020 14:58:42

US3392133

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:26:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:45
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 16:00:44
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	28 Sep 2020 14:58:42

US3392133

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:26:26

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:00:44
User entered '08:52'	Brenda Lawson (b) (4) (b) (4)	28 Sep 2020 14:58:42

US3392133

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:26:26

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User entered '28 Sep 2020 08:52'	System	28 Sep 2020 14:58:42

US3392133

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:26:26

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Brenda Lawson (b) (4)	28 Sep 2020 14:58:42

US3392133

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:26:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:00:44
User entered 'No (N)'	Brenda Lawson (b) (4) (b) (4)	28 Sep 2020 14:58:42

US3392133

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:26:26

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 16:00:44
User entered empty.	Brenda Lawson (b) (4) (b) (4)	28 Sep 2020 14:58:42

US3392133

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:26:26

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User entered empty.	System	28 Sep 2020 14:58:42

US3392133

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 04:40:45
DataPoint Verified.	(b) (4), (b) (6)	15 Oct 2020 16:00:55
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	28 Sep 2020 14:35:55

US3392133

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User entered 'I'	System	28 Sep 2020 14:35:55

US3392133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
Data entry locked.	System	28 Sep 2020 14:35:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Sep 2020 14:35:48

US3392133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:26:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-28T09:50:39', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'ecf5262f-40c6-4c8d-b361-3c7dd31064bf'	System	28 Sep 2020 14:50:56
User entered 'Yes (Y)'	System	28 Sep 2020 14:50:56

US3392133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:26:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-28T09:50:43', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'ecf5262f-40c6-4c8d-b361-3c7dd31064bf' User entered '98.3'	System	28 Sep 2020 14:50:56
	System	28 Sep 2020 14:50:56

US3392133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:26:26

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-28T09:50:47', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'ecf5262f-40c6-4c8d-b361-3c7dd31064bf'	System	28 Sep 2020 14:50:56
User entered 'No (N)'	System	28 Sep 2020 14:50:56

US3392133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:26:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-28T09:50:51', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'ecf5262f-40c6-4c8d-b361-3c7dd31064bf'	System	28 Sep 2020 14:50:56
User entered '28 Sep 2020 09:50'	System	28 Sep 2020 14:50:56

US3392133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:26:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '28 Sep 2020 09:48'	System	28 Sep 2020 14:35:48

US3392133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:26:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '28 Sep 2020 12:18'	System	28 Sep 2020 14:35:48

US3392133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
Data entry locked.	System	28 Sep 2020 14:35:48
User entered 'Day 1, after vaccination (at home)'	System	28 Sep 2020 14:35:48

US3392133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:26:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-28T13:13:34', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'ee374834-e603-4cbf-8880-7788ab80e8fb'	System	28 Sep 2020 18:13:49
User entered 'Yes (Y)'	System	28 Sep 2020 18:13:49

US3392133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:26:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-28T13:13:39', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'ee374834-e603-4cbf-8880-7788ab80e8fb' User entered '98.3'	System	28 Sep 2020 18:13:49
	System	28 Sep 2020 18:13:49

US3392133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:26:26

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-28T13:13:43', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'ee374834-e603-4cbf-8880-7788ab80e8fb'	System	28 Sep 2020 18:13:49
User entered 'No (N)'	System	28 Sep 2020 18:13:49

US3392133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:26:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-28T13:13:46', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'ee374834-e603-4cbf-8880-7788ab80e8fb'	System	28 Sep 2020 18:13:49
User entered '28 Sep 2020 13:13'	System	28 Sep 2020 18:13:49

US3392133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:26:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '28 Sep 2020 13:13'	System	28 Sep 2020 14:35:48

US3392133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:26:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '29 Sep 2020 11:59'	System	28 Sep 2020 14:35:48

US3392133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
Data entry locked.	System	28 Sep 2020 14:35:48
User entered 'Day 2'	System	28 Sep 2020 14:35:48

US3392133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:26:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-29T14:19:26', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'd9d1fe69-8113-4bea-a017-7dc73ccdb1f7'	System	29 Sep 2020 19:19:54
User entered 'Yes (Y)'	System	29 Sep 2020 19:19:54

US3392133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:26:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-29T14:19:36', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'd9d1fe69-8113-4bea-a017-7dc73ccdb1f7'	System	29 Sep 2020 19:19:54
User entered '102.1'	System	29 Sep 2020 19:19:54

US3392133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:26:26

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-29T14:19:40', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'd9d1fe69-8113-4bea-a017-7dc73ccdb1f7'	System	29 Sep 2020 19:19:54
User entered 'Yes (Y)'	System	29 Sep 2020 19:19:54

US3392133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:26:26

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'updated' (Site from System).	(b) (4), (b) (6)	04 Nov 2020 13:45:36
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). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-29T14:19:44', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'd9d1fe69-8113-4bea-a017-7dc73ccdb1f7'	Brandon Illickal (b) (4)	03 Nov 2020 21:58:52
User entered '1'	System	29 Sep 2020 19:19:54
	System	29 Sep 2020 19:19:54
	System	29 Sep 2020 19:19:54

US3392133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:26:26

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-29T14:19:44', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'd9d1fe69-8113-4bea-a017-7dc73ccdb1f7'	System	29 Sep 2020 19:19:54
User entered '0'	System	29 Sep 2020 19:19:54

US3392133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:26:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-29T14:19:49', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'd9d1fe69-8113-4bea-a017-7dc73ccdb1f7'	System	29 Sep 2020 19:19:54
User entered '29 Sep 2020 14:19'	System	29 Sep 2020 19:19:54

US3392133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:26:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 14:35:48

US3392133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:26:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 14:35:48

US3392133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
Data entry locked.	System	28 Sep 2020 14:35:48
User entered 'Day 3'	System	28 Sep 2020 14:35:48

US3392133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:26:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-30T12:39:59', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'ce7c8416-0e9a-4974-9905-69756e640cc3'	System	30 Sep 2020 17:40:22
User entered 'Yes (Y)'	System	30 Sep 2020 17:40:22

US3392133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:26:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-30T12:40:04', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'ce7c8416-0e9a-4974-9905-69756e640cc3'	System	30 Sep 2020 17:40:22
User entered '99.1'	System	30 Sep 2020 17:40:22

US3392133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:26:26

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-30T12:40:07', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'ce7c8416-0e9a-4974-9905-69756e640cc3'	System	30 Sep 2020 17:40:22
User entered 'Yes (Y)'	System	30 Sep 2020 17:40:22

US3392133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:26:26

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'updated' (Site from System).	(b) (4), (b) (6)	04 Nov 2020 13:45:56
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). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-30T12:40:13', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'ce7c8416-0e9a-4974-9905-69756e640cc3'	Brandon Illickal (b) (4)	03 Nov 2020 21:59:04
User entered '1'	System	30 Sep 2020 17:40:22

US3392133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:26:26

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-30T12:40:13', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'ce7c8416-0e9a-4974-9905-69756e640cc3' User entered '0'	System	30 Sep 2020 17:40:22
	System	30 Sep 2020 17:40:22

US3392133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:26:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-30T12:40:16', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'ce7c8416-0e9a-4974-9905-69756e640cc3'	System	30 Sep 2020 17:40:22
User entered '30 Sep 2020 12:40'	System	30 Sep 2020 17:40:22

US3392133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:26:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 14:35:48

US3392133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:26:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 14:35:48

US3392133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
Data entry locked.	System	28 Sep 2020 14:35:48
User entered 'Day 4'	System	28 Sep 2020 14:35:48

US3392133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:26:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:26:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:26:26

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:26:26

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:26:26

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:26:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:26:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '01 Oct 2020 12:00'	System	28 Sep 2020 14:35:48

US3392133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:26:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '02 Oct 2020 11:59'	System	28 Sep 2020 14:35:48

US3392133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
Data entry locked.	System	28 Sep 2020 14:35:48
User entered 'Day 5'	System	28 Sep 2020 14:35:48

US3392133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:26:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:26:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:26:26

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:26:26

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:26:26

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:26:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:26:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '02 Oct 2020 12:00'	System	28 Sep 2020 14:35:48

US3392133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:26:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '03 Oct 2020 11:59'	System	28 Sep 2020 14:35:48

US3392133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
Data entry locked.	System	28 Sep 2020 14:35:48
User entered 'Day 6'	System	28 Sep 2020 14:35:48

US3392133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:26:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:26:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:26:26

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:26:26

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:26:26

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:26:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:26:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '03 Oct 2020 12:00'	System	28 Sep 2020 14:35:48

US3392133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:26:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '04 Oct 2020 11:59'	System	28 Sep 2020 14:35:48

US3392133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
Data entry locked.	System	28 Sep 2020 14:35:48
User entered 'Day 7'	System	28 Sep 2020 14:35:48

US3392133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:26:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:26:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:26:26

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:26:26

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:26:26

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:26:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:26:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '04 Oct 2020 12:00'	System	28 Sep 2020 14:35:48

US3392133

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:26:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '05 Oct 2020 11:59'	System	28 Sep 2020 14:35:48

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
Data entry locked.	System	28 Sep 2020 14:35:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Sep 2020 14:35:48

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:26:26

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-28T09:50:55', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '5587cbe6-31f1-467f-a427-d378b1c86571'	System	28 Sep 2020 14:51:12
User entered 'None (1)'	System	28 Sep 2020 14:51:12

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:26:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-28T09:50:59', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '5587cbe6-31f1-467f-a427-d378b1c86571'	System	28 Sep 2020 14:51:12
User entered 'No (N)'	System	28 Sep 2020 14:51:12

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:26:26

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-28T09:51:01', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '5587cbe6-31f1-467f-a427-d378b1c86571'	System	28 Sep 2020 14:51:12
User entered 'No (N)'	System	28 Sep 2020 14:51:12

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:26:26

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-28T09:51:05', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '5587cbe6-31f1-467f-a427-d378b1c86571'	System	28 Sep 2020 14:51:12
User entered 'None (1)'	System	28 Sep 2020 14:51:12

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:26:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-28T09:51:08', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '5587cbe6-31f1-467f-a427-d378b1c86571'	System	28 Sep 2020 14:51:12
User entered '28 Sep 2020 09:51'	System	28 Sep 2020 14:51:12

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:26:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '28 Sep 2020 09:48'	System	28 Sep 2020 14:35:48

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:26:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '28 Sep 2020 12:18'	System	28 Sep 2020 14:35:48

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
Data entry locked.	System	28 Sep 2020 14:35:48
User entered 'Day 1, after vaccination (at home)'	System	28 Sep 2020 14:35:48

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:26:26

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-28T13:13:53', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '35474904-2949-418c-a3d5-72f155466511'	System	28 Sep 2020 18:14:15
User entered 'None (1)'	System	28 Sep 2020 18:14:15

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:26:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-28T13:13:55', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '35474904-2949-418c-a3d5-72f155466511'	System	28 Sep 2020 18:14:15
User entered 'No (N)'	System	28 Sep 2020 18:14:15

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:26:26

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-28T13:13:58', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '35474904-2949-418c-a3d5-72f155466511'	System	28 Sep 2020 18:14:15
User entered 'No (N)'	System	28 Sep 2020 18:14:15

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:26:26

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-28T13:14:01', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '35474904-2949-418c-a3d5-72f155466511'	System	28 Sep 2020 18:14:15
User entered 'None (1)'	System	28 Sep 2020 18:14:15

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:26:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-28T13:14:12', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '35474904-2949-418c-a3d5-72f155466511'	System	28 Sep 2020 18:14:15
User entered '28 Sep 2020 13:14'	System	28 Sep 2020 18:14:15

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:26:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '28 Sep 2020 13:13'	System	28 Sep 2020 14:35:48

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:26:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '29 Sep 2020 11:59'	System	28 Sep 2020 14:35:48

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
Data entry locked.	System	28 Sep 2020 14:35:48
User entered 'Day 2'	System	28 Sep 2020 14:35:48

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:26:26

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-29T14:20:03', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '04918d8d-e7bc-493a-920d-4bdb82a83df7'	System	29 Sep 2020 19:20:25
User entered 'Does not interfere with activity (2)'	System	29 Sep 2020 19:20:25

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:26:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-29T14:20:07', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '04918d8d-e7bc-493a-920d-4bdb82a83df7'	System	29 Sep 2020 19:20:25
User entered 'No (N)'	System	29 Sep 2020 19:20:25

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:26:26

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-29T14:20:10', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '04918d8d-e7bc-493a-920d-4bdb82a83df7'	System	29 Sep 2020 19:20:25
User entered 'No (N)'	System	29 Sep 2020 19:20:25

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:26:26

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-29T14:20:15', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '04918d8d-e7bc-493a-920d-4bdb82a83df7'	System	29 Sep 2020 19:20:25
User entered 'None (1)'	System	29 Sep 2020 19:20:25

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:26:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-29T14:20:19', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '04918d8d-e7bc-493a-920d-4bdb82a83df7'	System	29 Sep 2020 19:20:25
User entered '29 Sep 2020 14:20'	System	29 Sep 2020 19:20:25

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:26:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 14:35:48

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:26:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 14:35:48

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
Data entry locked.	System	28 Sep 2020 14:35:48
User entered 'Day 3'	System	28 Sep 2020 14:35:48

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:26:26

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-30T12:40:20', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'b8f34f25-1e22-4ccc-bcb5-14ef5f1d081d'	System	30 Sep 2020 17:40:37
User entered 'None (1)'	System	30 Sep 2020 17:40:37

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:26:26

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-30T12:40:22', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'b8f34f25-1e22-4ccc-bcb5-14ef5f1d081d'	System	30 Sep 2020 17:40:37
User entered 'No (N)'	System	30 Sep 2020 17:40:37

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:26:26

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-30T12:40:24', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'b8f34f25-1e22-4ccc-bcb5-14ef5f1d081d'	System	30 Sep 2020 17:40:37
User entered 'No (N)'	System	30 Sep 2020 17:40:37

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:26:26

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-30T12:40:26', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'b8f34f25-1e22-4ccc-bcb5-14ef5f1d081d'	System	30 Sep 2020 17:40:37
User entered 'None (1)'	System	30 Sep 2020 17:40:37

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:26:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-30T12:40:29', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'b8f34f25-1e22-4ccc-bcb5-14ef5f1d081d'	System	30 Sep 2020 17:40:37
User entered '30 Sep 2020 12:40'	System	30 Sep 2020 17:40:37

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:26:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 14:35:48

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:26:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 14:35:48

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
Data entry locked.	System	28 Sep 2020 14:35:48
User entered 'Day 4'	System	28 Sep 2020 14:35:48

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:26:26

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:26:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:26:26

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:26:26

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:26:26

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:26:26

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:26:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:26:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '01 Oct 2020 12:00'	System	28 Sep 2020 14:35:48

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:26:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '02 Oct 2020 11:59'	System	28 Sep 2020 14:35:48

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
Data entry locked.	System	28 Sep 2020 14:35:48
User entered 'Day 5'	System	28 Sep 2020 14:35:48

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:26:26

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:26:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:26:26

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:26:26

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:26:26

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:26:26

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:26:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:26:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '02 Oct 2020 12:00'	System	28 Sep 2020 14:35:48

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:26:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '03 Oct 2020 11:59'	System	28 Sep 2020 14:35:48

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
Data entry locked.	System	28 Sep 2020 14:35:48
User entered 'Day 6'	System	28 Sep 2020 14:35:48

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:26:26

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:26:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:26:26

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:26:26

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:26:26

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:26:26

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:26:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:26:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '03 Oct 2020 12:00'	System	28 Sep 2020 14:35:48

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:26:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '04 Oct 2020 11:59'	System	28 Sep 2020 14:35:48

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
Data entry locked.	System	28 Sep 2020 14:35:48
User entered 'Day 7'	System	28 Sep 2020 14:35:48

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:26:26

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:26:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:26:26

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:26:26

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:26:26

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:26:26

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:26:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:26:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '04 Oct 2020 12:00'	System	28 Sep 2020 14:35:48

US3392133

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:26:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '05 Oct 2020 11:59'	System	28 Sep 2020 14:35:48

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
Data entry locked.	System	28 Sep 2020 14:35:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Sep 2020 14:35:48

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:26:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-28T09:51:13', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'd335d8eb-a397-48f1-b2e3-ac9f4b4945eb'	System	28 Sep 2020 14:51:33
User entered 'None (0)'	System	28 Sep 2020 14:51:33

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:26:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-28T09:51:15', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'd335d8eb-a397-48f1-b2e3-ac9f4b4945eb'	System	28 Sep 2020 14:51:33
User entered 'None (0)'	System	28 Sep 2020 14:51:33

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:26:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-28T09:51:17', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'd335d8eb-a397-48f1-b2e3-ac9f4b4945eb'	System	28 Sep 2020 14:51:33
User entered 'None (0)'	System	28 Sep 2020 14:51:33

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:26:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-28T09:51:20', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'd335d8eb-a397-48f1-b2e3-ac9f4b4945eb'	System	28 Sep 2020 14:51:33
User entered 'None (0)'	System	28 Sep 2020 14:51:33

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:26:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-28T09:51:22', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'd335d8eb-a397-48f1-b2e3-ac9f4b4945eb'	System	28 Sep 2020 14:51:33
User entered 'None (0)'	System	28 Sep 2020 14:51:33

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:26:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-28T09:51:23', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'd335d8eb-a397-48f1-b2e3-ac9f4b4945eb'	System	28 Sep 2020 14:51:33
User entered 'None (0)'	System	28 Sep 2020 14:51:33

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:26:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-28T09:51:26', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'd335d8eb-a397-48f1-b2e3-ac9f4b4945eb'	System	28 Sep 2020 14:51:33
User entered 'No (N)'	System	28 Sep 2020 14:51:33

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:26:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-28T09:51:29', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'd335d8eb-a397-48f1-b2e3-ac9f4b4945eb'	System	28 Sep 2020 14:51:33
User entered '28 Sep 2020 09:51'	System	28 Sep 2020 14:51:33

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:26:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '28 Sep 2020 09:48'	System	28 Sep 2020 14:35:48

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:26:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '28 Sep 2020 12:18'	System	28 Sep 2020 14:35:48

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
Data entry locked.	System	28 Sep 2020 14:35:48
User entered 'Day 1, after vaccination (at home)'	System	28 Sep 2020 14:35:48

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:26:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-28T13:14:18', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '19821e75-7bdc-4995-ae34-7fdda7e42ed5'	System	28 Sep 2020 18:14:44
User entered 'None (0)'	System	28 Sep 2020 18:14:44

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:26:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-28T13:14:22', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '19821e75-7bdc-4995-ae34-7fdda7e42ed5'	System	28 Sep 2020 18:14:44
User entered 'None (0)'	System	28 Sep 2020 18:14:44

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:26:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-28T13:14:24', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '19821e75-7bdc-4995-ae34-7fdda7e42ed5'	System	28 Sep 2020 18:14:44
User entered 'None (0)'	System	28 Sep 2020 18:14:44

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:26:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-28T13:14:26', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '19821e75-7bdc-4995-ae34-7fdda7e42ed5'	System	28 Sep 2020 18:14:44
User entered 'None (0)'	System	28 Sep 2020 18:14:44

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:26:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-28T13:14:28', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '19821e75-7bdc-4995-ae34-7fdda7e42ed5'	System	28 Sep 2020 18:14:44
User entered 'None (0)'	System	28 Sep 2020 18:14:44

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:26:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-28T13:14:30', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '19821e75-7bdc-4995-ae34-7fdda7e42ed5'	System	28 Sep 2020 18:14:44
User entered 'None (0)'	System	28 Sep 2020 18:14:44

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:26:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-28T13:14:33', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '19821e75-7bdc-4995-ae34-7fdda7e42ed5'	System	28 Sep 2020 18:14:44
User entered 'No (N)'	System	28 Sep 2020 18:14:44

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:26:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-28T13:14:36', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '19821e75-7bdc-4995-ae34-7fdda7e42ed5'	System	28 Sep 2020 18:14:44
User entered '28 Sep 2020 13:14'	System	28 Sep 2020 18:14:44

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:26:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '28 Sep 2020 13:13'	System	28 Sep 2020 14:35:48

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:26:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '29 Sep 2020 11:59'	System	28 Sep 2020 14:35:48

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
Data entry locked.	System	28 Sep 2020 14:35:48
User entered 'Day 2'	System	28 Sep 2020 14:35:48

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:26:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-29T14:20:36', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'f6ed449a-32b1-44ed-aa23-b2d24eec03aa'	System	29 Sep 2020 19:21:29
User entered 'None (0)'	System	29 Sep 2020 19:21:29

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:26:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-29T14:20:45', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'f6ed449a-32b1-44ed-aa23-b2d24eec03aa'	System	29 Sep 2020 19:21:29
User entered 'Some interference with activity (2)'	System	29 Sep 2020 19:21:29

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:26:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-29T14:20:49', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'f6ed449a-32b1-44ed-aa23-b2d24eec03aa'	System	29 Sep 2020 19:21:29
User entered 'Some interference with activity (2)'	System	29 Sep 2020 19:21:29

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:26:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-29T14:20:51', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'f6ed449a-32b1-44ed-aa23-b2d24eec03aa'	System	29 Sep 2020 19:21:29
User entered 'Some interference with activity (2)'	System	29 Sep 2020 19:21:29

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:26:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-29T14:20:59', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'f6ed449a-32b1-44ed-aa23-b2d24eec03aa'	System	29 Sep 2020 19:21:29
User entered 'None (0)'	System	29 Sep 2020 19:21:29

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:26:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-29T14:21:15', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'f6ed449a-32b1-44ed-aa23-b2d24eec03aa'	System	29 Sep 2020 19:21:29
User entered 'Some interference with activity not requiring medical attention (2)'	System	29 Sep 2020 19:21:29

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:26:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-29T14:21:21', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'f6ed449a-32b1-44ed-aa23-b2d24eec03aa'	System	29 Sep 2020 19:21:29
User entered 'Yes (Y)'	System	29 Sep 2020 19:21:29

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:26:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-29T14:21:25', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'f6ed449a-32b1-44ed-aa23-b2d24eec03aa'	System	29 Sep 2020 19:21:29
User entered '29 Sep 2020 14:21'	System	29 Sep 2020 19:21:29

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:26:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 14:35:48

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:26:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 14:35:48

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
Data entry locked.	System	28 Sep 2020 14:35:48
User entered 'Day 3'	System	28 Sep 2020 14:35:48

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:26:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-30T12:40:33', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '9c0976d2-c5ad-40a3-b11b-536d60696c62'	System	30 Sep 2020 17:40:59
User entered 'None (0)'	System	30 Sep 2020 17:40:59

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:26:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-30T12:40:38', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '9c0976d2-c5ad-40a3-b11b-536d60696c62'	System	30 Sep 2020 17:40:59
User entered 'No interference with activity (1)'	System	30 Sep 2020 17:40:59

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:26:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-30T12:40:43', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '9c0976d2-c5ad-40a3-b11b-536d60696c62'	System	30 Sep 2020 17:40:59
User entered 'None (0)'	System	30 Sep 2020 17:40:59

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:26:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-30T12:40:44', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '9c0976d2-c5ad-40a3-b11b-536d60696c62'	System	30 Sep 2020 17:40:59
User entered 'None (0)'	System	30 Sep 2020 17:40:59

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:26:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-30T12:40:46', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '9c0976d2-c5ad-40a3-b11b-536d60696c62'	System	30 Sep 2020 17:40:59
User entered 'None (0)'	System	30 Sep 2020 17:40:59

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:26:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-30T12:40:50', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '9c0976d2-c5ad-40a3-b11b-536d60696c62'	System	30 Sep 2020 17:40:59
User entered 'No interference with activity (1)'	System	30 Sep 2020 17:40:59

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:26:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-30T12:40:54', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '9c0976d2-c5ad-40a3-b11b-536d60696c62'	System	30 Sep 2020 17:40:59
User entered 'No (N)'	System	30 Sep 2020 17:40:59

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:26:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-09-30T12:40:56', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '9c0976d2-c5ad-40a3-b11b-536d60696c62'	System	30 Sep 2020 17:40:59
User entered '30 Sep 2020 12:40'	System	30 Sep 2020 17:40:59

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:26:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 14:35:48

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:26:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 14:35:48

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
Data entry locked.	System	28 Sep 2020 14:35:48
User entered 'Day 4'	System	28 Sep 2020 14:35:48

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:26:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:26:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:26:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:26:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:26:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:26:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:26:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:26:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:26:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '01 Oct 2020 12:00'	System	28 Sep 2020 14:35:48

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:26:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '02 Oct 2020 11:59'	System	28 Sep 2020 14:35:48

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
Data entry locked.	System	28 Sep 2020 14:35:48
User entered 'Day 5'	System	28 Sep 2020 14:35:48

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:26:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:26:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:26:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:26:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:26:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:26:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:26:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:26:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:26:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '02 Oct 2020 12:00'	System	28 Sep 2020 14:35:48

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:26:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '03 Oct 2020 11:59'	System	28 Sep 2020 14:35:48

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
Data entry locked.	System	28 Sep 2020 14:35:48
User entered 'Day 6'	System	28 Sep 2020 14:35:48

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:26:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:26:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:26:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:26:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:26:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:26:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:26:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:26:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:26:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '03 Oct 2020 12:00'	System	28 Sep 2020 14:35:48

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:26:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '04 Oct 2020 11:59'	System	28 Sep 2020 14:35:48

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
Data entry locked.	System	28 Sep 2020 14:35:48
User entered 'Day 7'	System	28 Sep 2020 14:35:48

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:26:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:26:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:26:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:26:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:26:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:26:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:26:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:26:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:26:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '04 Oct 2020 12:00'	System	28 Sep 2020 14:35:48

US3392133

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:26:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:37:50
User entered '05 Oct 2020 11:59'	System	28 Sep 2020 14:35:48

US3392133

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:56:50
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:41:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 20:18:37

US3392133

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:26

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:56:50
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:41:56
User entered '5 Oct 2020'	(b) (4), (b) (6)	05 Oct 2020 20:18:37

US3392133

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:56:50
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:41:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	05 Oct 2020 20:18:37

US3392133

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:56:50
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:41:56
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 20:18:37

US3392133

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:56:50
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:42:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 20:19:10

US3392133

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User entered 'I'	System	05 Oct 2020 20:19:10

US3392133

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:40:36
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:42:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 21:28:27

US3392133

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:26

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:40:36
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:42:24
User entered '12 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 21:28:27

US3392133

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:40:36
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:42:24
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	12 Oct 2020 21:28:27

US3392133

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:40:36
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:42:24
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 21:28:27

US3392133

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:40:36
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:42:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 21:28:31

US3392133

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User entered 'I'	System	12 Oct 2020 21:28:31

US3392133

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:23:14
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:43:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 20:06:01

US3392133

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:26

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:23:14
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:43:27
User entered '19 Oct 2020'	(b) (4), (b) (6)	19 Oct 2020 20:06:01

US3392133

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:23:14
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:43:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	19 Oct 2020 20:06:01

US3392133

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:23:14
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:43:27
User entered empty.	(b) (4), (b) (6)	19 Oct 2020 20:06:01

US3392133

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User signature succeeded.	Michael Cotugno (b) (4)	20 Feb 2021 01:23:14
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:43:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 20:06:05

US3392133

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User entered 'I'	System	19 Oct 2020 20:06:05

US3392133

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:26:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:22:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:43:44
User entered 'Yes (Y)'	Lois Eaglin (b) (4)	23 Oct 2020 13:58:08

US3392133

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:26:26

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:22:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 19:43:44
User entered '23 Oct 2020'	Lois Eaglin (b) (4)	23 Oct 2020 13:58:08

US3392133

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:26:26

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:22:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:43:44
User entered 'Clinic (Clinic)'	Lois Eaglin (b) (4)	23 Oct 2020 13:58:08

US3392133

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:26:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User entered 'VISIT3'	System	23 Oct 2020 13:58:08

US3392133

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:22:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 19:43:52
User entered 'No (N)'	Lois Eaglin (b) (4)	23 Oct 2020 13:58:15

US3392133

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:22:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:43:52
User entered empty.	Lois Eaglin (b) (4)	23 Oct 2020 13:58:15

US3392133

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:26

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:22:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:43:52
User entered empty.	Lois Eaglin (b) (4)	23 Oct 2020 13:58:15

US3392133

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:26

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User entered empty.	System	23 Oct 2020 13:58:15

US3392133

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:22:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:43:52
User entered empty.	Lois Eaglin (b) (4)	23 Oct 2020 13:58:15

US3392133

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:22:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:43:52
User entered empty.	Lois Eaglin (b) (4)	23 Oct 2020 13:58:15

US3392133

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:22:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:43:52
User entered empty.	Lois Eaglin (b) (4)	23 Oct 2020 13:58:15

US3392133

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:22:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:43:52
User entered empty.	Lois Eaglin (b) (4)	23 Oct 2020 13:58:15

US3392133

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User entered empty.	System	23 Oct 2020 13:58:15

US3392133

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:26

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:22:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:43:52
User entered empty.	Lois Eaglin (b) (4)	23 Oct 2020 13:58:15

US3392133

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User entered empty.	System	23 Oct 2020 13:58:15

US3392133

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:22:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:43:52
User entered empty.	Lois Eaglin (b) (4)	23 Oct 2020 13:58:15

US3392133

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User entered empty.	System	23 Oct 2020 13:58:15

US3392133

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:22:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 19:43:52
User entered empty.	Lois Eaglin (b) (4)	23 Oct 2020 13:58:15

US3392133

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User entered empty.	System	23 Oct 2020 13:58:15

US3392133

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:26

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02

US3392133

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:26

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02

US3392133

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:26:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:22:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 19:44:00
User entered 'No (N)'	Lois Eaglin (b) (4)	23 Oct 2020 13:58:22

US3392133

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:26:26

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:22:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:44:00
User entered empty.	Lois Eaglin (b) (4)	23 Oct 2020 13:58:22

US3392133

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:26:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:22:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:44:22
User entered 'Yes (Y)'	Lois Eaglin (b) (4)	23 Oct 2020 13:58:38

US3392133

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:26:26

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:22:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 19:44:22
User entered '23 Oct 2020'	Lois Eaglin (b) (4)	23 Oct 2020 13:58:38

US3392133

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:26:26

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:22:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:44:22
User entered '08:11'	Lois Eaglin (b) (4)	23 Oct 2020 13:58:38

US3392133

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:26:26

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User entered '23 Oct 2020 08:11'	System	23 Oct 2020 13:58:38

US3392133

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User signature succeeded.	Michael Cotugno (b) (4)	21 Feb 2021 05:22:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 19:44:30
User entered 'Yes (Y)'	Lois Eaglin (b) (4)	23 Oct 2020 13:58:45

US3392133

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User entered '1'	System	23 Oct 2020 13:58:45

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01
Data entry locked.	System	01 Sep 2020 15:39:00
User entered 'Day 64'	System	01 Sep 2020 15:39:00

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01
Data entry locked.	System	01 Sep 2020 15:39:00
User entered '01 Nov 2020 00:01'	System	01 Sep 2020 15:39:00

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01
Data entry locked.	System	01 Sep 2020 15:39:00
User entered '05 Nov 2020 23:59'	System	01 Sep 2020 15:39:00

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01
Data entry locked.	System	01 Sep 2020 15:39:00
User entered 'Day 71'	System	01 Sep 2020 15:39:00

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01
Data entry locked.	System	01 Sep 2020 15:39:00
User entered '08 Nov 2020 00:01'	System	01 Sep 2020 15:39:00

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01
Data entry locked.	System	01 Sep 2020 15:39:00
User entered '12 Nov 2020 23:59'	System	01 Sep 2020 15:39:00

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01
Data entry locked.	System	01 Sep 2020 15:39:00
User entered 'Day 78'	System	01 Sep 2020 15:39:00

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01
Data entry locked.	System	01 Sep 2020 15:39:00
User entered '15 Nov 2020 00:01'	System	01 Sep 2020 15:39:00

US3392133

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:35:01
Data entry locked.	System	01 Sep 2020 15:39:00
User entered '19 Nov 2020 23:59'	System	01 Sep 2020 15:39:00

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-11-20T16:15:37', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '4aeefc0f-becc-407b-ae6-29f8998d34a3'	System	20 Nov 2020 22:15:59
User entered 'No (N)'	System	20 Nov 2020 22:15:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-11-20T16:15:50', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '4aeefc0f-becc-407b-ae6-29f8998d34a3'	System	20 Nov 2020 22:15:59
User entered 'No (N)'	System	20 Nov 2020 22:15:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-11-20T16:15:53', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '4aeefc0f-becc-407b-ae6-29f8998d34a3'	System	20 Nov 2020 22:15:59
User entered '20 Nov 2020 16:15:53'	System	20 Nov 2020 22:15:59

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-11-26T06:49:13', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '36c93993-f8ba-4510-98ec-774f57072d7e'	System	26 Nov 2020 12:49:34
User entered 'No (N)'	System	26 Nov 2020 12:49:34

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-11-26T06:49:26', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '36c93993-f8ba-4510-98ec-774f57072d7e'	System	26 Nov 2020 12:49:34
User entered 'No (N)'	System	26 Nov 2020 12:49:34

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-11-26T06:49:31', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '36c93993-f8ba-4510-98ec-774f57072d7e' User entered '26 Nov 2020 06:49:31'	System	26 Nov 2020 12:49:34
	System	26 Nov 2020 12:49:34

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-12-03T06:45:03', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'ddd7d342-8c75-469a-b0ac-a60dd2a5d94f'	System	03 Dec 2020 12:45:38
User entered 'No (N)'	System	03 Dec 2020 12:45:38

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-12-03T06:45:27', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'ddd7d342-8c75-469a-b0ac-a60dd2a5d94f'	System	03 Dec 2020 12:45:38
User entered 'No (N)'	System	03 Dec 2020 12:45:38

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-12-03T06:45:35', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'ddd7d342-8c75-469a-b0ac-a60dd2a5d94f'	System	03 Dec 2020 12:45:38
User entered '03 Dec 2020 06:45:35'	System	03 Dec 2020 12:45:38

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-12-10T20:33:19', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'a74766ab-bf15-4e93-b61b-5aa25894e5fe'	System	11 Dec 2020 02:33:28
User entered 'No (N)'	System	11 Dec 2020 02:33:28

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-12-10T20:33:22', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'a74766ab-bf15-4e93-b61b-5aa25894e5fe'	System	11 Dec 2020 02:33:28
User entered 'No (N)'	System	11 Dec 2020 02:33:28

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-12-10T20:33:25', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'a74766ab-bf15-4e93-b61b-5aa25894e5fe'	System	11 Dec 2020 02:33:28
User entered '10 Dec 2020 20:33:25'	System	11 Dec 2020 02:33:28

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-12-17T07:38:03', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '9f010ff5-f610-4fbb-ab42-003f5daa1b8d'	System	17 Dec 2020 13:38:17
User entered 'No (N)'	System	17 Dec 2020 13:38:17

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-12-17T07:38:08', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '9f010ff5-f610-4fbb-ab42-003f5daa1b8d'	System	17 Dec 2020 13:38:17
User entered 'No (N)'	System	17 Dec 2020 13:38:17

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-12-17T07:38:12', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '9f010ff5-f610-4fbb-ab42-003f5daa1b8d' User entered '17 Dec 2020 07:38:12'	System	17 Dec 2020 13:38:17
	System	17 Dec 2020 13:38:17

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-12-31T00:04:28', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'fbccf606-4a66-4d54-951b-8fb1ee2aecf4'	System	31 Dec 2020 06:04:43
User entered 'No (N)'	System	31 Dec 2020 06:04:43

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-12-31T00:04:33', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'fbccf606-4a66-4d54-951b-8fb1ee2aecf4'	System	31 Dec 2020 06:04:43
User entered 'No (N)'	System	31 Dec 2020 06:04:43

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2020-12-31T00:04:37', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'fbccf606-4a66-4d54-951b-8fb1ee2aecf4' User entered '31 Dec 2020 00:04:37'	System	31 Dec 2020 06:04:43
	System	31 Dec 2020 06:04:43

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2021-01-07T04:00:09', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'feb73d13-e951-47e0-bc5f-9775bc4c9eae'	System	07 Jan 2021 10:00:33
User entered 'No (N)'	System	07 Jan 2021 10:00:33

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2021-01-07T04:00:24', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'feb73d13-e951-47e0-bc5f-9775bc4c9eae'	System	07 Jan 2021 10:00:33
User entered 'No (N)'	System	07 Jan 2021 10:00:33

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2021-01-07T04:00:27', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'feb73d13-e951-47e0-bc5f-9775bc4c9eae' User entered '07 Jan 2021 04:00:27'	System	07 Jan 2021 10:00:33
	System	07 Jan 2021 10:00:33

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2021-01-14T08:33:00', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '30493e1a-ca00-4d9a-b9ff-cd38d7a8a4cc'	System	14 Jan 2021 14:33:13
User entered 'No (N)'	System	14 Jan 2021 14:33:13

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2021-01-14T08:33:04', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '30493e1a-ca00-4d9a-b9ff-cd38d7a8a4cc'	System	14 Jan 2021 14:33:13
User entered 'No (N)'	System	14 Jan 2021 14:33:13

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2021-01-14T08:33:08', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '30493e1a-ca00-4d9a-b9ff-cd38d7a8a4cc' User entered '14 Jan 2021 08:33:08'	System	14 Jan 2021 14:33:13

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2021-01-21T00:24:54', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'a9a782d3-cb70-4e3e-99ef-0225be3ec77b'	System	21 Jan 2021 06:25:06
User entered 'No (N)'	System	21 Jan 2021 06:25:06

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2021-01-21T00:24:57', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'a9a782d3-cb70-4e3e-99ef-0225be3ec77b'	System	21 Jan 2021 06:25:06
User entered 'No (N)'	System	21 Jan 2021 06:25:06

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2021-01-21T00:25:01', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'a9a782d3-cb70-4e3e-99ef-0225be3ec77b'	System	21 Jan 2021 06:25:06
User entered '21 Jan 2021 00:25:01'	System	21 Jan 2021 06:25:06

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a38afe5a26c1010)', Time: '2021-01-30T12:00:39', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '56709833-0dda-449d-a823-60235d064c9c'	System	30 Jan 2021 18:01:43
User entered 'No (N)'	System	30 Jan 2021 18:01:43

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a38afe5a26c1010)', Time: '2021-01-30T12:00:52', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '56709833-0dda-449d-a823-60235d064c9c'	System	30 Jan 2021 18:01:43
User entered 'No (N)'	System	30 Jan 2021 18:01:43

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a38afe5a26c1010)', Time: '2021-01-30T12:01:01', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '56709833-0dda-449d-a823-60235d064c9c'	System	30 Jan 2021 18:01:43
User entered '30 Jan 2021 12:01:01'	System	30 Jan 2021 18:01:43

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a38afe5a26c1010)', Time: '2021-02-04T19:01:14', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'aa66d1d0-316b-4f04-9121-9a63282c90bd'	System	05 Feb 2021 01:01:28
User entered 'No (N)'	System	05 Feb 2021 01:01:28

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a38afe5a26c1010)', Time: '2021-02-04T19:01:18', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'aa66d1d0-316b-4f04-9121-9a63282c90bd'	System	05 Feb 2021 01:01:28
User entered 'No (N)'	System	05 Feb 2021 01:01:28

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a38afe5a26c1010)', Time: '2021-02-04T19:01:25', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'aa66d1d0-316b-4f04-9121-9a63282c90bd'	System	05 Feb 2021 01:01:28
User entered '04 Feb 2021 19:01:25'	System	05 Feb 2021 01:01:28

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a38afe5a26c1010)', Time: '2021-02-12T17:47:21', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '04838dea-dc96-4b19-a4aa-14218b4d54f2'	System	12 Feb 2021 23:47:30
User entered 'No (N)'	System	12 Feb 2021 23:47:30

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a38afe5a26c1010)', Time: '2021-02-12T17:47:24', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '04838dea-dc96-4b19-a4aa-14218b4d54f2'	System	12 Feb 2021 23:47:30
User entered 'No (N)'	System	12 Feb 2021 23:47:30

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a38afe5a26c1010)', Time: '2021-02-12T17:47:27', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '04838dea-dc96-4b19-a4aa-14218b4d54f2'	System	12 Feb 2021 23:47:30
User entered '12 Feb 2021 17:47:27'	System	12 Feb 2021 23:47:30

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a38afe5a26c1010)', Time: '2021-02-19T15:21:52', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'a303c604-0297-408a-add9-298c30dfd49f'	System	19 Feb 2021 21:22:04
User entered 'No (N)'	System	19 Feb 2021 21:22:04

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a38afe5a26c1010)', Time: '2021-02-19T15:21:54', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'a303c604-0297-408a-add9-298c30dfd49f'	System	19 Feb 2021 21:22:04
User entered 'No (N)'	System	19 Feb 2021 21:22:04

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9a38afe5a26c1010)', Time: '2021-02-19T15:21:57', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'a303c604-0297-408a-add9-298c30dfd49f' User entered '19 Feb 2021 15:21:57'	System	19 Feb 2021 21:22:04
	System	19 Feb 2021 21:22:04

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2021-02-25T06:40:10-06:00', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'a254f46a-4d15-4abf-93c0-39d17506dd1e' User entered 'No (N)'	System	25 Feb 2021 12:40:25
	System	25 Feb 2021 12:40:25

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2021-02-25T06:40:13-06:00', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'a254f46a-4d15-4abf-93c0-39d17506dd1e' User entered 'No (N)'	System	25 Feb 2021 12:40:25
	System	25 Feb 2021 12:40:25

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2021-02-25T06:40:17-06:00', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'a254f46a-4d15-4abf-93c0-39d17506dd1e' User entered '25 Feb 2021 06:40:17'	System	25 Feb 2021 12:40:25
	System	25 Feb 2021 12:40:25

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2021-03-07T14:43:11-06:00', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '37c0ae89-705f-4c86-8615-f5ad6253ab35'	System	07 Mar 2021 20:43:22
User entered 'No (N)'	System	07 Mar 2021 20:43:22

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2021-03-07T14:43:14-06:00', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '37c0ae89-705f-4c86-8615-f5ad6253ab35'	System	07 Mar 2021 20:43:22
User entered 'No (N)'	System	07 Mar 2021 20:43:22

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2021-03-07T14:43:17-06:00', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '37c0ae89-705f-4c86-8615-f5ad6253ab35' User entered '07 Mar 2021 14:43:17'	System	07 Mar 2021 20:43:22
	System	07 Mar 2021 20:43:22

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2021-03-18T08:55:41-05:00', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'b3b71187-bac4-45c6-9aa8-f5a8116fe3cf' User entered 'Yes (Y)'	System	18 Mar 2021 13:57:05
	System	18 Mar 2021 13:57:05

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2021-03-18T08:55:40-05:00', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'b3b71187-bac4-45c6-9aa8-f5a8116fe3cf' User entered 'No (N)'	System	18 Mar 2021 13:57:05

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2021-03-18T08:55:44-05:00', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'b3b71187-bac4-45c6-9aa8-f5a8116fe3cf' User entered 'No (N)'	System	18 Mar 2021 13:57:05
	System	18 Mar 2021 13:57:05

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2021-03-18T08:56:32-05:00', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'b3b71187-bac4-45c6-9aa8-f5a8116fe3cf' User entered 'Yes (Y)'	System	18 Mar 2021 13:57:05

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2021-03-18T08:56:39-05:00', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'b3b71187-bac4-45c6-9aa8-f5a8116fe3cf'	System	18 Mar 2021 13:57:05
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	18 Mar 2021 13:57:05

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2021-03-18T08:56:51-05:00', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'b3b71187-bac4-45c6-9aa8-f5a8116fe3cf' User entered '18 Mar 2021 08:56:51'	System	18 Mar 2021 13:57:05
	System	18 Mar 2021 13:57:05

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2021-03-27T10:55:57-05:00', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'fd8d6e15-d12f-4470-b590-3acd8b1032ec'	System	27 Mar 2021 15:56:08
User entered 'No (N)'	System	27 Mar 2021 15:56:08

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2021-03-27T10:56:00-05:00', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'fd8d6e15-d12f-4470-b590-3acd8b1032ec'	System	27 Mar 2021 15:56:08
User entered 'No (N)'	System	27 Mar 2021 15:56:08

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2021-03-27T10:56:03-05:00', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'fd8d6e15-d12f-4470-b590-3acd8b1032ec' User entered '27 Mar 2021 10:56:03'	System	27 Mar 2021 15:56:08
	System	27 Mar 2021 15:56:08

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2021-04-01T09:14:50-05:00', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '58bf4bc7-01b6-4459-a358-146cf7ad9464'	System	01 Apr 2021 14:15:03
User entered 'No (N)'	System	01 Apr 2021 14:15:03

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2021-04-01T09:14:55-05:00', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '58bf4bc7-01b6-4459-a358-146cf7ad9464'	System	01 Apr 2021 14:15:03
User entered 'No (N)'	System	01 Apr 2021 14:15:03

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2021-04-01T09:14:58-05:00', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '58bf4bc7-01b6-4459-a358-146cf7ad9464'	System	01 Apr 2021 14:15:03
User entered '01 Apr 2021 09:14:58'	System	01 Apr 2021 14:15:03

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2021-04-09T13:12:57-05:00', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'a521b6d0-d414-4ac3-ab99-992691d10597'	System	09 Apr 2021 18:13:09
User entered 'No (N)'	System	09 Apr 2021 18:13:09

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2021-04-09T13:13:02-05:00', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'a521b6d0-d414-4ac3-ab99-992691d10597'	System	09 Apr 2021 18:13:09
User entered 'No (N)'	System	09 Apr 2021 18:13:09

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2021-04-09T13:13:06-05:00', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'a521b6d0-d414-4ac3-ab99-992691d10597'	System	09 Apr 2021 18:13:09
User entered '09 Apr 2021 13:13:06'	System	09 Apr 2021 18:13:09

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2021-04-15T08:26:23-05:00', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'f2a3729e-a0a1-440c-8d63-7e2f77c00965'	System	15 Apr 2021 13:26:35
User entered 'No (N)'	System	15 Apr 2021 13:26:35

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2021-04-15T08:26:27-05:00', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'f2a3729e-a0a1-440c-8d63-7e2f77c00965'	System	15 Apr 2021 13:26:35
User entered 'No (N)'	System	15 Apr 2021 13:26:35

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2021-04-15T08:26:31-05:00', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'f2a3729e-a0a1-440c-8d63-7e2f77c00965' User entered '15 Apr 2021 08:26:31'	System	15 Apr 2021 13:26:35
	System	15 Apr 2021 13:26:35

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2021-04-23T14:02:37-05:00', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '9a823403-e28b-4e66-b1c9-827e51cdcb7f' User entered 'No (N)'	System	23 Apr 2021 19:03:18
	System	23 Apr 2021 19:03:18

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2021-04-23T14:02:40-05:00', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '9a823403-e28b-4e66-b1c9-827e51cdcb7f' User entered 'No (N)'	System	23 Apr 2021 19:03:18
	System	23 Apr 2021 19:03:18

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2021-04-23T14:02:43-05:00', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '9a823403-e28b-4e66-b1c9-827e51cdcb7f' User entered '23 Apr 2021 14:02:43'	System	23 Apr 2021 19:03:18
	System	23 Apr 2021 19:03:18

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2021-04-29T09:24:52-05:00', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'a515b543-cd7d-4587-87bf-be6c43799d0a' User entered 'No (N)'	System	29 Apr 2021 14:45:38
	System	29 Apr 2021 14:45:38

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2021-04-29T09:24:55-05:00', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'a515b543-cd7d-4587-87bf-be6c43799d0a'	System	29 Apr 2021 14:45:38
User entered 'No (N)'	System	29 Apr 2021 14:45:38

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2021-04-29T09:24:58-05:00', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: 'a515b543-cd7d-4587-87bf-be6c43799d0a'	System	29 Apr 2021 14:45:38
User entered '29 Apr 2021 09:24:58'	System	29 Apr 2021 14:45:38

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '13 Oct 2022 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '17 Oct 2022 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '20 Oct 2022 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '24 Oct 2022 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '27 Oct 2022 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '31 Oct 2022 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '03 Nov 2022 00:01'	System	19 Nov 2020 21:35:01

US3392133

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:35:01
Amendment Manager: User entered '07 Nov 2022 23:59'	System	19 Nov 2020 21:35:01

US3392133

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:26:26

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2021-03-02T13:34:14-06:00', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '055582c6-bbfe-413e-b4b2-6b5fa72043b1'	System	02 Mar 2021 19:34:22
User entered 'No (N)'	System	02 Mar 2021 19:34:22

US3392133

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:26:26

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:07:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d65707bfb448234c)', Time: '2021-03-02T13:34:17-06:00', User OID: 'PatientReportedOutcome (US3392133)', ODM File OID: '055582c6-bbfe-413e-b4b2-6b5fa72043b1' User entered '02 Mar 2021 13:34:17'	System	02 Mar 2021 19:34:22
	System	02 Mar 2021 19:34:22

US3392133

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User signature succeeded.	Michael Cotugno (b) (4)	08 Mar 2021 22:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 20:46:19
User entered 'Yes (Y)'	Brenda Lawson (b) (4) (b) (4)	14 Dec 2020 16:42:20

US3392133

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:26

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User signature succeeded.	Michael Cotugno (b) (4)	08 Mar 2021 22:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 20:46:19
User entered '20 Nov 2020'	Brenda Lawson (b) (4) (b) (4)	14 Dec 2020 16:42:20

US3392133

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User signature succeeded.	Michael Cotugno (b) (4)	08 Mar 2021 22:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 20:46:19
User entered 'Contact Made (CONTACT MADE)'	Brenda Lawson (b) (4) (b) (4)	14 Dec 2020 16:42:20

US3392133

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User signature succeeded.	Michael Cotugno (b) (4)	08 Mar 2021 22:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 20:46:19
User entered empty.	Brenda Lawson (b) (4) (b) (4)	14 Dec 2020 16:42:20

US3392133

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User signature succeeded.	Michael Cotugno (b) (4)	08 Mar 2021 22:56:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Jan 2021 20:46:28
User entered 'Yes (Y)'	Brenda Lawson (b) (4) (b) (4)	14 Dec 2020 16:42:36

US3392133

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:50:02
User entered 'I'	System	14 Dec 2020 16:42:36

US3392133

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:40:23
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:33
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:02:06
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	14 Dec 2020 16:42:52

US3392133

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:26

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:40:23
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:33
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:02:06
User entered '14 Dec 2020'	Brenda Lawson (b) (4)	14 Dec 2020 16:42:52

US3392133

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:40:23
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:33
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:02:06
User entered 'Contact Made (CONTACT MADE)'	Brenda Lawson (b) (4)	14 Dec 2020 16:42:52

US3392133

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:40:23
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:33
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:02:06
User entered empty.	Brenda Lawson (b) (4)	14 Dec 2020 16:42:52

US3392133

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:40:23
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:33
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:02:11
User entered 'Yes (Y)'	Brenda Lawson (b) (4)	14 Dec 2020 16:43:02

US3392133

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:40:23
User entered 'I'	System	14 Dec 2020 16:43:02

US3392133

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:00:55
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:02:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Feb 2021 21:30:16

US3392133

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:26

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:00:55
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:02:42
User entered '25 Jan 2021'	(b) (4), (b) (6)	05 Feb 2021 21:30:16

US3392133

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:00:55
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:02:42
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	05 Feb 2021 21:30:16

US3392133

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:00:55
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:02:42
User entered empty.	(b) (4), (b) (6)	05 Feb 2021 21:30:16

US3392133

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:00:55
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:03:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Feb 2021 21:30:23

US3392133

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:00:55
User entered 'I'	System	05 Feb 2021 21:30:23

US3392133

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:18
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:03:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Feb 2021 00:03:31

US3392133

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:26

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:18
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:33
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:03:41
User entered '22 Feb 2021'	(b) (4), (b) (6)	23 Feb 2021 00:03:31

US3392133

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:18
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:03:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	23 Feb 2021 00:03:31

US3392133

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:18
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:33
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:03:41
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 00:03:31

US3392133

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:18
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:04:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Feb 2021 00:04:20

US3392133

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:44:18
User entered 'I'	System	23 Feb 2021 00:04:20

US3392133

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:26:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:21
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:02:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Mar 2021 21:02:07

US3392133

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:26:26

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:21
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:02:03
User entered '24 Mar 2021'	(b) (4), (b) (6)	24 Mar 2021 21:02:07

US3392133

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:26:26

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:21
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:02:03
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	24 Mar 2021 21:02:07

US3392133

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:26:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:21
User entered 'VISIT4'	System	24 Mar 2021 21:02:07

US3392133

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:21
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:58:56
User entered 'No (N)'	(b) (4), (b) (6)	02 Apr 2021 16:20:58

US3392133

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:21
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:58:56
User entered empty.	(b) (4), (b) (6)	02 Apr 2021 16:20:58

US3392133

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:26

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:21
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:58:56
User entered empty.	(b) (4), (b) (6)	02 Apr 2021 16:20:58

US3392133

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:26

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:21
User entered empty.	System	02 Apr 2021 16:20:58

US3392133

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:21
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:58:56
User entered empty.	(b) (4), (b) (6)	02 Apr 2021 16:20:58

US3392133

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:21
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:58:56
User entered empty.	(b) (4), (b) (6)	02 Apr 2021 16:20:58

US3392133

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:21
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:58:56
User entered empty.	(b) (4), (b) (6)	02 Apr 2021 16:20:58

US3392133

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:21
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:58:56
User entered empty.	(b) (4), (b) (6)	02 Apr 2021 16:20:58

US3392133

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:21
User entered empty.	System	02 Apr 2021 16:20:58

US3392133

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:26

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:21
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:58:56
User entered empty.	(b) (4), (b) (6)	02 Apr 2021 16:20:58

US3392133

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:21
User entered empty.	System	02 Apr 2021 16:20:58

US3392133

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:26

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:21
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:58:56
User entered empty.	(b) (4), (b) (6)	02 Apr 2021 16:20:58

US3392133

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:21
User entered empty.	System	02 Apr 2021 16:20:58

US3392133

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:21
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:58:56
User entered empty.	(b) (4), (b) (6)	02 Apr 2021 16:20:58

US3392133

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:21
User entered empty.	System	02 Apr 2021 16:20:58

US3392133

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:26

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:21

US3392133

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:26

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:21

US3392133

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:26:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:21
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:02:11
User entered 'No (N)'	(b) (4), (b) (6)	24 Mar 2021 21:02:11

US3392133

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:26:26

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:21
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:02:11
User entered empty.	(b) (4), (b) (6)	24 Mar 2021 21:02:11

US3392133

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:26:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:21
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:02:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Mar 2021 21:02:21

US3392133

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:26:26

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:21
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:02:17
User entered '24 Mar 2021'	(b) (4), (b) (6)	24 Mar 2021 21:02:21

US3392133

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:26:26

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:21
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:02:17
User entered '15:22'	(b) (4), (b) (6)	24 Mar 2021 21:02:21

US3392133

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:26:26

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:21
User entered '24 Mar 2021 15:22'	System	24 Mar 2021 21:02:21

US3392133

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:21
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:02:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Mar 2021 21:02:27

US3392133

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:14:21
User entered 'I'	System	24 Mar 2021 21:02:27

US3392133

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:18:15

US3392133

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:26

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:33
User entered '23 Apr 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:18:15

US3392133

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:33
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:18:15

US3392133

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:33
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:18:15

US3392133

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:18:23

US3392133

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:26

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Apr 2021 17:18:23

US3392133

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:26:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:17
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:04:48
User entered 'Yes (Y)'	Brenda Lawson (b) (4) (b) (4)	25 Jan 2021 22:23:15

US3392133

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:26:26

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:17
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:04:48
User entered '25 Jan 2021'	Brenda Lawson (b) (4) (b) (4)	25 Jan 2021 22:23:15

US3392133

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:26:26

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:17
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:04:48
User entered 'Clinic (Clinic)'	Brenda Lawson (b) (4) (b) (4)	25 Jan 2021 22:23:15

US3392133

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:26:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:17
User entered 'UNBLND_DECIDE'	System	25 Jan 2021 22:23:15

US3392133

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:26:26

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:17
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:04:53
User entered '25 Jan 2021'	Brenda Lawson (b) (4) (b) (4)	25 Jan 2021 22:23:46

US3392133

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:26:26

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:17
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:59:15
User entered '0'	(b) (4), (b) (6)	08 Apr 2021 20:10:16
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 07:45:48

US3392133

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:26:26

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:17
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:04:53
User entered 'Yes (Y)'	Brenda Lawson (b) (4) (b) (4)	25 Jan 2021 22:23:46

US3392133

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:26:26

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:17
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 14:59:15
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	08 Apr 2021 20:10:16
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 07:45:48

US3392133

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:26:26

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:17
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:04:53
User entered '25 Jan 2021'	Brenda Lawson (b) (4) (b) (4)	25 Jan 2021 22:23:46

US3392133

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:26:26

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:17
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:04:53
User entered 'mRNA-1273 (mRNA-1273)'	Brenda Lawson (b) (4) (b) (4)	25 Jan 2021 22:23:46

US3392133

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:26:26

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:17
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:04:53
User entered 'mRNA-1273 (mRNA-1273)'	Brenda Lawson (b) (4) (b) (4)	25 Jan 2021 22:23:46

US3392133

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:26:26

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:17
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:04:53
User entered 'mRNA-1273 (mRNA-1273)'	Brenda Lawson (b) (4) (b) (4)	25 Jan 2021 22:23:46

US3392133

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:26:26

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:17
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:04:53
User entered 'No (N)'	Brenda Lawson (b) (4) (b) (4)	25 Jan 2021 22:23:46

US3392133

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:26:26

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:17
User entered empty.	System	25 Jan 2021 22:23:46

US3392133

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:26:26

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:17
User entered empty.	System	25 Jan 2021 22:23:46

US3392133

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:26:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:17
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:05:16
User entered 'Yes (Y)'	Brenda Lawson (b) (4) (b) (4)	25 Jan 2021 22:24:09

US3392133

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:26:26

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:17
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:05:16
User entered '25 Jan 2021'	Brenda Lawson (b) (4) (b) (4)	25 Jan 2021 22:24:09

US3392133

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:26:26

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:17
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:05:16
User entered '12:27'	Brenda Lawson (b) (4) (b) (4)	25 Jan 2021 22:24:09

US3392133

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:26:26

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:17
User entered '25 Jan 2021 12:27'	System	25 Jan 2021 22:24:09

US3392133

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:26:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:17
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:05:24
User entered 'Yes (Y)'	Brenda Lawson (b) (4) (b) (4)	25 Jan 2021 22:24:25

US3392133

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:26:26

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:17
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:05:24
User entered '25 Jan 2021'	Brenda Lawson (b) (4) (b) (4)	25 Jan 2021 22:24:25

US3392133

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:26:26

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:17
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:17:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:05:24
User entered '12:29'	Brenda Lawson (b) (4) (b) (4)	25 Jan 2021 22:24:25

US3392133

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:26:26

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:07:17
User entered '25 Jan 2021 12:29'	System	25 Jan 2021 22:24:25

US3392133

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:26:26

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:28:33
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:09:22
User closed query 'Per CDM: "Did participant experience any adverse event" recorded "No" however adverse events are recorded on corresponding page. Please review and update accordingly, else clarify. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 12:26:51
Query 'Per CDM: "Did participant experience any adverse event" recorded "No" however adverse event are recorded on corresponding page. Please review and update accordingly, else clarify. ' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 15:46:30
DataPoint Un-verified.	(b) (4), (b) (6)	29 Mar 2021 15:46:13
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Mar 2021 15:46:13
User opened query 'Per CDM: "Did participant experience any adverse event" recorded "No" however adverse events are recorded on corresponding page. Please review and update accordingly, else clarify. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 20:16:19
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:05:41
User entered 'No (N)' reason for change: Data Entry Error	Brandon Illickal (b) (4)	31 Jan 2021 04:41:33
User entered 'Yes (Y)'	Brandon Illickal (b) (4)	05 Oct 2020 20:42:27

US3392133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:26

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 12:20:05
Un-reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 12:19:54
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:14
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:09:40
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 12:07:47
User entered 'USA-US119-2021-mRNA-1273-P301000008'	System	19 Mar 2021 12:07:38
User entered 'New'	(b) (4), (b) (6)	19 Mar 2021 12:07:38

US3392133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:26

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:09:40
User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial flutter, LLT: Atrial flutter - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Mar 2021 18:11:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Mar 2021 18:11:05
Data point term sent to Coder	System	18 Mar 2021 18:09:52
User entered 'atrial flutter'	Brandon Illickal (b) (4)	18 Mar 2021 18:09:14

US3392133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:26

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:09:40
User entered 'Yes (Y)'	Brandon Illickal (b) (4)	18 Mar 2021 18:09:14

US3392133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:26

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:09:40
User entered 'No (N)'	Brandon Illickal (b) (4) 	18 Mar 2021 18:09:14

US3392133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:26

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:09:40
User entered 'No (N)'	Brandon Illickal (b) (4)	18 Mar 2021 18:09:14

US3392133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:09:40
User entered '09 Mar 2021'	Brandon Illickal (b) (4)	18 Mar 2021 18:09:14

US3392133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:26

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:09:40
User entered empty.	Brandon Illickal (b) (4)	18 Mar 2021 18:09:14

US3392133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:26

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Mar 2021 18:09:14

US3392133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:26

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:09:40
User entered 'No (N)'	Brandon Illickal (b) (4)	18 Mar 2021 18:09:14

US3392133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:26

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:09:40
User entered '12 Mar 2021'	Brandon Illickal (b) (4)	18 Mar 2021 18:09:14

US3392133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:26

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:09:40
User entered empty.	Brandon Illickal (b) (4)	18 Mar 2021 18:09:14

US3392133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:26

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Mar 2021 18:09:14

US3392133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:26

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:09:40
User entered 'Grade 3/Severe (Grade 3/Severe)'	Brandon Illickal (b) (4) 	18 Mar 2021 18:09:14

US3392133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:26

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:09:40
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	18 Mar 2021 18:09:42
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	18 Mar 2021 18:09:14
User entered 'Yes (Y)'	Brandon Illickal (b) (4)	18 Mar 2021 18:09:14

US3392133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:26

Death

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:09:40
User entered '0'	Brandon Illickal (b) (4)	18 Mar 2021 18:09:14

US3392133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:26

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:09:40
User entered '0'	Brandon Illickal (b) (4)	18 Mar 2021 18:09:14

US3392133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:26

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
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). User signature succeeded.	(b) (4), (b) (6)	29 Apr 2021 12:18:11
	Michael Cotugno (b) (4)	28 Apr 2021 22:06:14
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 'Medical records sent to Moderna' (Site from Safety).	Brandon Illickal (b) (4)	28 Apr 2021 17:23:39
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)	07 Apr 2021 20:22:35
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)	07 Apr 2021 20:22:35
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 'Waiting on hospital records' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 15:57:04
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)	06 Apr 2021 13:00:12
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:09:40

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	18 Mar 2021 18:09:42
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	18 Mar 2021 18:09:42
User entered '1' reason for change: Per Query Resolution	Brandon Illickal (b) (4) [REDACTED] [REDACTED]	18 Mar 2021 18:09:42
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	18 Mar 2021 18:09:14
User entered '0'	Brandon Illickal (b) (4) [REDACTED] [REDACTED]	18 Mar 2021 18:09:14

US3392133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:26

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:09:40
User entered '09 Mar 2021'	Brandon Illickal (b) (4)	18 Mar 2021 18:09:14

US3392133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:26

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:09:40
User entered '12 Mar 2021'	Brandon Illickal (b) (4)	18 Mar 2021 18:09:14

US3392133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:26

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:09:40
User entered 'No (N)'	Brandon Illickal (b) (4)	18 Mar 2021 18:09:14

US3392133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:26

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:09:40
User entered empty.	Brandon Illickal (b) (4)	18 Mar 2021 18:09:14

US3392133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:09:40
User entered '0'	Brandon Illickal (b) (4)	18 Mar 2021 18:09:14

US3392133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:09:40
User entered '0'	Brandon Illickal (b) (4)	18 Mar 2021 18:09:14

US3392133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:26

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:09:40
User entered '0'	Brandon Illickal (b) (4)	18 Mar 2021 18:09:14

US3392133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:26

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:09:40
User entered 'Not Related (NOT RELATED)'	Brandon Illickal (b) (4) 	18 Mar 2021 18:09:14

US3392133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:26

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:09:40
User entered 'Not Related (NOT RELATED)'	Brandon Illickal (b) (4) 	18 Mar 2021 18:09:14

US3392133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:26

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:09:40
User entered 'Not Applicable (NOT APPLICABLE)'	Brandon Illickal (b) (4) 	18 Mar 2021 18:09:14

US3392133

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:26

None

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:09:40
User entered '0'	Brandon Illickal (b) (4)	18 Mar 2021 18:09:14

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:26

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:09:40
User closed query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Mar 2021 13:33:34
Query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' answered with 'Con mends added to eCRF' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 15:48:47
User opened query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 20:50:06
User entered 'I'	Brandon Illickal (b) (4)	18 Mar 2021 18:09:14

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:26

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:14
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:09:40
User entered '0'	Brandon Illickal (b) (4)	18 Mar 2021 18:09:14

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:26

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:09:40
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Brandon Illickal (b) (4)	18 Mar 2021 18:09:14

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:26

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:09:40
User entered empty.	Brandon Illickal (b) (4)	18 Mar 2021 18:09:14

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:26

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 19:11:32
User closed query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 12:18:42
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 12:18:37
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. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 12:18:31
User signature succeeded.	Michael Cotugno (b) (4)	28 Apr 2021 22:06:14
Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event. Please leave query open until information is available.' answered with 'no underlying conditions or predisposing risk factors' (Site from Safety).	Brandon Illickal (b) (4)	28 Apr 2021 17:31:42
DataPoint Un-verified.	Brandon Illickal (b) (4)	28 Apr 2021 17:31:07
User entered 'SUBJECT WAS ADMITTED TO EMERGENCY DEPARTMENT WITH ATRIAL FLUTTER.' reason for change: Data Entry Error	Brandon Illickal (b) (4)	28 Apr 2021 17:31:07
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. Please leave query open until information is available.' answered with 'Medical records have been sent to Moderna' (Site from Safety).	Brandon Illickal (b) (4)	28 Apr 2021 17:27:19

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:26

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. Please leave query open until information is available.' answered with 'Medical records sent to Moderna. Subject COVID-19 result was Negative' (Site from Safety).	Brandon Illickal (b) (4)	28 Apr 2021 17:26:41
User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	07 Apr 2021 20:22:18
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)	07 Apr 2021 20:22:18
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	07 Apr 2021 20:21:37
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)	07 Apr 2021 20:21:37
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. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	07 Apr 2021 20:20:53
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)	07 Apr 2021 20:20:53
User closed query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	07 Apr 2021 20:19:59
Query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' answered with 'No medical history.' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 15:59:14

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:26

[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 'Waiting on hospital records.' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 15:58:52
Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' answered with 'Waiting on hospital records.' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 15:58:37
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 'Waiting on hospital records.' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 15:58:23
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)	06 Apr 2021 12:59:58
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)	06 Apr 2021 12:59:50
User opened query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 12:59:38
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 12:59:29
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)	31 Mar 2021 21:57:58
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)	31 Mar 2021 21:57:55
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)	31 Mar 2021 21:57:27

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:26

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	31 Mar 2021 21:57:24
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)	31 Mar 2021 21:57:20
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)	31 Mar 2021 21:57:07
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 21:09:40
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 'Medical records not yet available' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 15:50:38
Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event. ' answered with 'Medical records not yet available' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 15:50:27
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' answered with 'Medical records not yet available' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 15:50:23
Query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' answered with 'Medical records not yet available' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 15:50:19

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:26

[Narrative](#)

Audit	User	Time (GMT)
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 'Medical records not yet available' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 15:50:15
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' answered with 'Hospital records not yet available' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 15:49:41
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)	25 Mar 2021 20:49:54
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)	25 Mar 2021 20:49:43
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)	25 Mar 2021 20:49:35
User opened query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 20:49:23
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)	25 Mar 2021 20:48:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:26

[Narrative](#)

Audit	User	Time (GMT)
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)	25 Mar 2021 20:48:22
User entered 'subject was admitted to emergency department with atrial flutter. will update when hospital records are received.'	Brandon Illickal (b) (4)	18 Mar 2021 18:09:14

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:26

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Mar 2021 18:09:14

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:26

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Mar 2021 18:09:14

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:26:26

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	18 Mar 2021 18:09:14

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:26:26

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:28:33
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:05:56
User entered 'Yes (Y)' reason for change: Data Entry Error	Brandon Illickal (b) (4)	06 Oct 2020 14:09:48
User entered 'No (N)'	Brandon Illickal (b) (4)	01 Sep 2020 14:41:16

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:26:26

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:00:13
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:08:22
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)	06 Oct 2020 14:14:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 14:14:53
Data point term sent to Coder	System	06 Oct 2020 14:11:17
User entered 'Tylenol'	Brandon Illickal (b) (4)	06 Oct 2020 14:10:46

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:26:26

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:00:13
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:08:22
User entered 'No (N)'	Brandon Illickal (b) (4)	06 Oct 2020 14:10:46

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:26:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:00:13
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:08:22
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the VACCINE-INDUCED FEVER is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of VACCINE-INDUCED FEVER did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 05:46:51
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the VACCINE-INDUCED FEVER is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of VACCINE-INDUCED FEVER did not meet the AE reporting criteria.' answered with 'AE updated' (Site from DM).	Heather Salisbury (b) (4)	04 Dec 2020 22:12:12

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:26:26

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the VACCINE-INDUCED FEVER is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of VACCINE-INDUCED FEVER did not meet the AE reporting criteria.' (Site from DM). User entered 'Vaccine-induced fever'	(b) (4), (b) (6) [REDACTED] Brandon Illickal (b) (4) [REDACTED] [REDACTED]	29 Nov 2020 15:15:57 06 Oct 2020 14:10:46

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:26:26

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:00:13
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:08:22
User entered '1000'	Brandon Illickal (b) (4)	06 Oct 2020 14:10:46

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:26:26

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:00:13
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:08:22
User entered 'mg (mg)'	Brandon Illickal (b) (4)	06 Oct 2020 14:10:46

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:26:26

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:00:13
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:08:22
User entered empty.	Brandon Illickal (b) (4)	06 Oct 2020 14:10:46

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:26:26

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:00:13
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:08:22
User entered 'as needed (PRN)'	Brandon Illickal (b) (4)	06 Oct 2020 14:10:46

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:26:26

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:00:13
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:08:22
User entered empty.	Brandon Illickal (b) (4)	06 Oct 2020 14:10:46

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:26:26

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:00:13
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:08:22
User entered 'Oral (ORAL)'	Brandon Illickal (b) (4)	06 Oct 2020 14:10:46

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:26:26

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:00:13
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:08:22
User entered empty.	Brandon Illickal (b) (4)	06 Oct 2020 14:10:46

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:26:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:00:13
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:08:22
User entered '29 Sep 2020'	Brandon Illickal (b) (4)	06 Oct 2020 14:10:46

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:26:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:00:13
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:08:22
User entered '0'	Brandon Illickal (b) (4)	06 Oct 2020 14:10:46

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:26:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:00:13
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:08:22
User entered 'No (N)'	Brandon Illickal (b) (4)	06 Oct 2020 14:10:46

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:26:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:00:13
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:08:22
User entered '30 Sep 2020'	Brandon Illickal (b) (4)	06 Oct 2020 14:10:46

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:26:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:00:13
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:08:22
User entered 'Yes (Y)'	Brandon Illickal (b) (4)	06 Oct 2020 14:10:46

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:26:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:00:13
User entered empty.	System	06 Oct 2020 14:10:46

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:26:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:00:13
User entered empty.	System	06 Oct 2020 14:10:46

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:26:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:00:13
User entered empty.	System	06 Oct 2020 14:10:46

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:26:26

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:11:36
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 09:07:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 09:07:32
Data point term sent to Coder	System	29 Mar 2021 15:27:28
User entered 'Apixaban'	(b) (4), (b) (6)	29 Mar 2021 15:27:09

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:26:26

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered 'No (N)'	(b) (4), (b) (6)	29 Mar 2021 15:27:09

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:26:26

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered 'Atrial Flutter'	(b) (4), (b) (6)	29 Mar 2021 15:27:09

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:26:26

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered '5'	(b) (4), (b) (6)	29 Mar 2021 15:27:09

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:26:26

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered 'mg (mg)'	(b) (4), (b) (6)	29 Mar 2021 15:27:09

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:26:26

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 15:27:09

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:26:26

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered 'twice daily (BID)'	(b) (4), (b) (6)	29 Mar 2021 15:27:09

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:26:26

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 15:27:09

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:26:26

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	29 Mar 2021 15:27:09

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:26:26

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 15:27:09

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:26:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered '12 Mar 2021'	(b) (4), (b) (6)	29 Mar 2021 15:27:09

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:26:26

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered '0'	(b) (4), (b) (6)	29 Mar 2021 15:27:09

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:26:26

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Mar 2021 15:27:09

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:26:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 15:27:09

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:26:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered 'No (N)'	(b) (4), (b) (6)	29 Mar 2021 15:27:09

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:26:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	29 Mar 2021 15:27:09

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:26:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Mar 2021 15:27:09

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:26:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Mar 2021 15:27:09

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:26:26

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:11:36
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: CARDIAC GLYCOSIDES, ATC: DIGITALIS GLYCOSIDES, PRODUCT: DIGOXIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 00:45:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 00:45:21
Data point term sent to Coder	System	29 Mar 2021 15:29:29
User entered 'Digoxin'	(b) (4), (b) (6)	29 Mar 2021 15:29:02

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:26:26

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered 'No (N)'	(b) (4), (b) (6)	29 Mar 2021 15:29:02

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:26:26

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered 'Atrial Flutter'	(b) (4), (b) (6)	29 Mar 2021 15:29:02

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:26:26

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered '0.25'	(b) (4), (b) (6)	29 Mar 2021 15:29:02

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:26:26

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered 'mg (mg)'	(b) (4), (b) (6)	29 Mar 2021 15:29:02

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:26:26

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 15:29:02

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:26:26

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered 'once daily (QD)'	(b) (4), (b) (6)	29 Mar 2021 15:29:02

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:26:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 15:29:02

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:26:26

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	29 Mar 2021 15:29:02

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:26:26

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 15:29:02

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:26:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered '12 Mar 2021'	(b) (4), (b) (6)	29 Mar 2021 15:29:02

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:26:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered '0'	(b) (4), (b) (6)	29 Mar 2021 15:29:02

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:26:26

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Mar 2021 15:29:02

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:26:26

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 15:29:02

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:26:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered 'No (N)'	(b) (4), (b) (6)	29 Mar 2021 15:29:02

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:26:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Mar 2021 15:29:02

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:26:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Mar 2021 15:29:02

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:26:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Mar 2021 15:29:02

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:26:26

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:11:36
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 14:08:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 14:08:09
Data point term sent to Coder	System	29 Mar 2021 15:31:33
User entered 'Furosemide'	(b) (4), (b) (6)	29 Mar 2021 15:31:22

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:26:26

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered 'No (N)'	(b) (4), (b) (6)	29 Mar 2021 15:31:22

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:26:26

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered 'Atrial Flutter'	(b) (4), (b) (6)	29 Mar 2021 15:31:22

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:26:26

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered '20'	(b) (4), (b) (6)	29 Mar 2021 15:31:22

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:26:26

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered 'mg (mg)'	(b) (4), (b) (6)	29 Mar 2021 15:31:22

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:26:26

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 15:31:22

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:26:26

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered 'once daily (QD)'	(b) (4), (b) (6)	29 Mar 2021 15:31:22

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:26:26

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 15:31:22

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:26:26

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	29 Mar 2021 15:31:22

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:26:26

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 15:31:22

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:26:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered '12 Mar 2021'	(b) (4), (b) (6)	29 Mar 2021 15:31:22

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:26:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered '0'	(b) (4), (b) (6)	29 Mar 2021 15:31:22

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:26:26

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Mar 2021 15:31:22

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:26:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 15:31:22

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:26:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered 'No (N)'	(b) (4), (b) (6)	29 Mar 2021 15:31:22

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:26:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Mar 2021 15:31:22

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:26:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Mar 2021 15:31:22

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:26:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Mar 2021 15:31:22

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:26:26

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:11:36
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)	29 Mar 2021 15:42:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 15:42:17
Data point term sent to Coder	System	29 Mar 2021 15:40:50
User entered 'Metoprolol'	(b) (4), (b) (6)	29 Mar 2021 15:40:28

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:26:26

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered 'No (N)'	(b) (4), (b) (6)	29 Mar 2021 15:40:28

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:26:26

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered 'Atrial Flutter'	(b) (4), (b) (6)	29 Mar 2021 15:40:28

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:26:26

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered '50'	(b) (4), (b) (6)	29 Mar 2021 15:40:28

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:26:26

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered 'mg (mg)'	(b) (4), (b) (6)	29 Mar 2021 15:40:28

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:26:26

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 15:40:28

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:26:26

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered 'once daily (QD)'	(b) (4), (b) (6)	29 Mar 2021 15:40:28

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:26:26

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 15:40:28

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:26:26

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	29 Mar 2021 15:40:28

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:26:26

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 15:40:28

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:26:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered '12 Mar 2021'	(b) (4), (b) (6)	29 Mar 2021 15:40:28

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:26:26

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered '0'	(b) (4), (b) (6)	29 Mar 2021 15:40:28

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:26:26

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Mar 2021 15:40:28

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:26:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 15:40:28

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:26:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered 'No (N)'	(b) (4), (b) (6)	29 Mar 2021 15:40:28

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:26:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Mar 2021 15:40:28

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:26:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Mar 2021 15:40:28

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:26:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Mar 2021 15:40:28

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:26:26

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:11:36
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)	29 Mar 2021 15:42:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 15:42:18
Data point term sent to Coder	System	29 Mar 2021 15:41:51
User entered 'Metoprolol'	(b) (4), (b) (6)	29 Mar 2021 15:41:23

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:26:26

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered 'No (N)'	(b) (4), (b) (6)	29 Mar 2021 15:41:23

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:26:26

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered 'Atrial Flutter'	(b) (4), (b) (6)	29 Mar 2021 15:41:23

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:26:26

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered '25'	(b) (4), (b) (6)	29 Mar 2021 15:41:23

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:26:26

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered 'mg (mg)'	(b) (4), (b) (6)	29 Mar 2021 15:41:23

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:26:26

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 15:41:23

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:26:26

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered 'once daily (QD)'	(b) (4), (b) (6)	29 Mar 2021 15:41:23

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:26:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 15:41:23

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:26:26

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	29 Mar 2021 15:41:23

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:26:26

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 15:41:23

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:26:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered '12 Mar 2021'	(b) (4), (b) (6)	29 Mar 2021 15:41:23

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:26:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered '0'	(b) (4), (b) (6)	29 Mar 2021 15:41:23

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:26:26

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Mar 2021 15:41:23

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:26:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 15:41:23

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:26:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered 'No (N)'	(b) (4), (b) (6)	29 Mar 2021 15:41:23

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:26:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Mar 2021 15:41:23

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:26:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Mar 2021 15:41:23

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:26:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Mar 2021 15:41:23

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:26:26

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:11:36
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), COMBINATIONS, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), OTHER COMBINATIONS, PRODUCT: SACUBITRIL;VALSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 08:43:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 08:43:23
Data point term sent to Coder	System	29 Mar 2021 15:44:56
User entered 'Sacubitril-valsartan'	(b) (4), (b) (6)	29 Mar 2021 15:44:44

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:26:26

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered 'No (N)'	(b) (4), (b) (6)	29 Mar 2021 15:44:44

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:26:26

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered 'Atrila Flutter'	(b) (4), (b) (6)	29 Mar 2021 15:44:44

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:26:26

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered '24-26'	(b) (4), (b) (6)	29 Mar 2021 15:44:44

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:26:26

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered 'mg (mg)'	(b) (4), (b) (6)	29 Mar 2021 15:44:44

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:26:26

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 15:44:44

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:26:26

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered 'twice daily (BID)'	(b) (4), (b) (6)	29 Mar 2021 15:44:44

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:26:26

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 15:44:44

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:26:26

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	29 Mar 2021 15:44:44

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:26:26

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 15:44:44

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:26:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered '12 Mar 2021'	(b) (4), (b) (6)	29 Mar 2021 15:44:44

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:26:26

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered '0'	(b) (4), (b) (6)	29 Mar 2021 15:44:44

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:26:26

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Mar 2021 15:44:44

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:26:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 15:44:44

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:26:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:11:36
User entered 'No (N)'	(b) (4), (b) (6)	29 Mar 2021 15:44:44

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:26:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	29 Mar 2021 15:44:44

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:26:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Mar 2021 15:44:44

US3392133

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:26:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Mar 2021 15:44:44

US3392133

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:26:26

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 19:10:24
User entered 'No (N)'	Brandon Illickal (b) (4) 	01 Sep 2020 14:41:23

US3392133

Folder: SAE USA-US119-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:26

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:09:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 12:09:11
User entered 'USA-US119-2021-MRNA-1273-P301000008'	System	19 Mar 2021 12:07:38

US3392133

Folder: SAE USA-US119-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:26

Serious

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:09:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 12:09:11
User entered 'Yes (Y)'	System	19 Mar 2021 12:07:38

US3392133

Folder: SAE USA-US119-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:26

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:09:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 12:09:11
User entered 'No (N)'	System	19 Mar 2021 12:07:38

US3392133

Folder: SAE USA-US119-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:26

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:09:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 12:09:11
User entered 'No (N)'	System	19 Mar 2021 12:07:38

US3392133

Folder: SAE USA-US119-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:09:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 12:09:11
User entered 'Yes (Y)'	System	19 Mar 2021 12:07:38

US3392133

Folder: SAE USA-US119-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:09:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 12:09:11
User entered 'No (N)'	System	19 Mar 2021 12:07:38

US3392133

Folder: SAE USA-US119-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:09:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 12:09:11
User entered 'No (N)'	System	19 Mar 2021 12:07:38

US3392133

Folder: SAE USA-US119-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:26

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:09:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 12:09:11
User entered 'No (N)'	System	19 Mar 2021 12:07:38

US3392133

Folder: SAE USA-US119-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:09:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 12:09:11
User entered 'Michael'	System	19 Mar 2021 12:07:38

US3392133

Folder: SAE USA-US119-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:09:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 12:09:11
User entered 'Cotugno'	System	19 Mar 2021 12:07:38

US3392133

Folder: SAE USA-US119-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:26

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:09:14
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:34:07
User entered 'US'	System	19 Mar 2021 12:09:25

US3392133

Folder: SAE USA-US119-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	29 Apr 2021 12:21:02
User entered '2'	System	30 Mar 2021 13:34:01
User entered '1'	System	19 Mar 2021 12:09:25

US3392133

Folder: SAE USA-US119-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:26

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:09:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 12:09:11
User entered 'USA-US119-2021-MRNA-1273-P301000008'	System	19 Mar 2021 12:07:38

US3392133

Folder: SAE USA-US119-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:26

Serious

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:09:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 12:09:11
User entered 'Yes (Y)'	System	19 Mar 2021 12:07:38

US3392133

Folder: SAE USA-US119-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:26

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:09:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 12:09:11
User entered 'No (N)'	System	19 Mar 2021 12:07:38

US3392133

Folder: SAE USA-US119-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:26

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:09:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 12:09:11
User entered 'No (N)'	System	19 Mar 2021 12:07:38

US3392133

Folder: SAE USA-US119-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:09:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 12:09:11
User entered 'Yes (Y)'	System	19 Mar 2021 12:07:38

US3392133

Folder: SAE USA-US119-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:09:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 12:09:11
User entered 'No (N)'	System	19 Mar 2021 12:07:38

US3392133

Folder: SAE USA-US119-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:09:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 12:09:11
User entered 'No (N)'	System	19 Mar 2021 12:07:38

US3392133

Folder: SAE USA-US119-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:26

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:09:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 12:09:11
User entered 'No (N)'	System	19 Mar 2021 12:07:38

US3392133

Folder: SAE USA-US119-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:09:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 12:09:11
User entered 'Michael'	System	19 Mar 2021 12:07:38

US3392133

Folder: SAE USA-US119-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:09:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 12:09:11
User entered 'Cotugno'	System	19 Mar 2021 12:07:38

US3392133

Folder: SAE USA-US119-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:26

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:09:14
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:34:07
User entered 'US'	System	19 Mar 2021 12:09:25

US3392133

Folder: SAE USA-US119-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	29 Apr 2021 12:21:02
User entered '2'	System	30 Mar 2021 13:34:01
User entered '1'	System	19 Mar 2021 12:09:25

US3392133

Folder: SAE USA-US119-2021-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:26:26

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:09:14
User entered '19/Mar/2021 12:09'	System	19 Mar 2021 12:09:25

US3392133

Folder: SAE USA-US119-2021-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:26:26

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:09:14
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:34:07
User entered 'I'	(b) (4), (b) (6)	19 Mar 2021 12:09:25

US3392133

Folder: SAE USA-US119-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:26

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:09:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 12:09:11
User entered 'USA-US119-2021-MRNA-1273-P301000008'	System	19 Mar 2021 12:07:38

US3392133

Folder: SAE USA-US119-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:26

Serious

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:09:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 12:09:11
User entered 'Yes (Y)'	System	19 Mar 2021 12:07:38

US3392133

Folder: SAE USA-US119-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:26

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:09:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 12:09:11
User entered 'No (N)'	System	19 Mar 2021 12:07:38

US3392133

Folder: SAE USA-US119-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:26

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:09:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 12:09:11
User entered 'No (N)'	System	19 Mar 2021 12:07:38

US3392133

Folder: SAE USA-US119-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:09:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 12:09:11
User entered 'Yes (Y)'	System	19 Mar 2021 12:07:38

US3392133

Folder: SAE USA-US119-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:09:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 12:09:11
User entered 'No (N)'	System	19 Mar 2021 12:07:38

US3392133

Folder: SAE USA-US119-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:09:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 12:09:11
User entered 'No (N)'	System	19 Mar 2021 12:07:38

US3392133

Folder: SAE USA-US119-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:26

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:09:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 12:09:11
User entered 'No (N)'	System	19 Mar 2021 12:07:38

US3392133

Folder: SAE USA-US119-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:09:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 12:09:11
User entered 'Michael'	System	19 Mar 2021 12:07:38

US3392133

Folder: SAE USA-US119-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:09:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 12:09:11
User entered 'Cotugno'	System	19 Mar 2021 12:07:38

US3392133

Folder: SAE USA-US119-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:26

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:09:14
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:34:07
User entered 'US'	System	19 Mar 2021 12:09:25

US3392133

Folder: SAE USA-US119-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	29 Apr 2021 12:21:02
User entered '2'	System	30 Mar 2021 13:34:01
User entered '1'	System	19 Mar 2021 12:09:25

US3392133

Folder: SAE USA-US119-2021-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:26:26

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:09:14
User entered '30/Mar/2021 09:34'	System	30 Mar 2021 13:34:01

US3392133

Folder: SAE USA-US119-2021-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:26:26

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:09:14
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:34:07
User entered 'I'	(b) (4), (b) (6)	30 Mar 2021 13:34:01

US3392133

Folder: SAE USA-US119-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:26

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:09:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 12:09:11
User entered		
'USA-US119-2021-MRNA-1273-P301000008'	System	19 Mar 2021 12:07:38

US3392133

Folder: SAE USA-US119-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:26

Serious

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:09:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 12:09:11
User entered 'Yes (Y)'	System	19 Mar 2021 12:07:38

US3392133

Folder: SAE USA-US119-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:26

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:09:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 12:09:11
User entered 'No (N)'	System	19 Mar 2021 12:07:38

US3392133

Folder: SAE USA-US119-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:26

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:09:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 12:09:11
User entered 'No (N)'	System	19 Mar 2021 12:07:38

US3392133

Folder: SAE USA-US119-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:09:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 12:09:11
User entered 'Yes (Y)'	System	19 Mar 2021 12:07:38

US3392133

Folder: SAE USA-US119-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:09:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 12:09:11
User entered 'No (N)'	System	19 Mar 2021 12:07:38

US3392133

Folder: SAE USA-US119-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:09:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 12:09:11
User entered 'No (N)'	System	19 Mar 2021 12:07:38

US3392133

Folder: SAE USA-US119-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:26

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:09:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 12:09:11
User entered 'No (N)'	System	19 Mar 2021 12:07:38

US3392133

Folder: SAE USA-US119-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:09:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 12:09:11
User entered 'Michael'	System	19 Mar 2021 12:07:38

US3392133

Folder: SAE USA-US119-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:09:14
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 12:09:11
User entered 'Cotugno'	System	19 Mar 2021 12:07:38

US3392133

Folder: SAE USA-US119-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:26

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 21:09:14
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 13:34:07
User entered 'US'	System	19 Mar 2021 12:09:25

US3392133

Folder: SAE USA-US119-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	29 Apr 2021 12:21:02
User entered '2'	System	30 Mar 2021 13:34:01
User entered '1'	System	19 Mar 2021 12:09:25

US3392133

Folder: SAE USA-US119-2021-MRNA-1273-P301000008

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:26:26

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 11:41:26
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
User entered '29/Apr/2021 08:21'	(b) (4) System	29 Apr 2021 12:21:02

US3392133

Folder: SAE USA-US119-2021-MRNA-1273-P301000008

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:26:26

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 11:41:26
User signature succeeded.	Michael Cotugno (b) (4)	29 Apr 2021 20:06:03
User entered 'I'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 12:21:02